Ex. 21

Rebecca Gibson

From:	Olivia Ray <oliviaray@ventaviaresearch.com>
Sent:	Monday, September 21, 2020 10:13 AM
To:	Kandy Downs; Mercedes Livingston; Brook Jackson
Cc:	Marnie Fisher; Kristi Raney; Katie Buchanan
Subject:	RE: Daily Status Calls Updates and Action Items
Attachments:	Daily Status Updates 9.19.2020.docx

Sorry I missed the last few minutes of the call. Please see attached.

Thanks,

Olivia Ray
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

www.ventaviaresearch.com

From: Olivia Ray
Sent: Friday, September 18, 2020 8:54 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

www.ventaviaresearch.com

PLATINUM
RESEARCH NETWORK

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 5:11 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Will do.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

VRG VENTAVIA RESEARCH GROUP
PLATINUM RESEARCH NETWORK

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 5:08 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

Kandy, to be clear, we want the RD's doing weekly or bi weekly touch points with the PI's. This is to check on the SOM's, site leads, staff, etc.

Olivia Ray
Managing Member, Executive Director

Ventavia Research Group
1307 8th Avenue, Suite 202
Fort Worth, TX 76104
t: 8173480228
m: 2143940772
e: oliviaray@ventaviaresearch.com

www.ventaviaresearch.com

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 5:01:12 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Kandy

- QC both unblinded logs at KEL and FW FW done 9/17 Keller 9/18 to be completed.
- **Get ARL's screening visits canceled so Becca can immediately QC Keller Jennifer had 1 only visit-Becca sent to Keller**
- **Get Plano's visits handled by Precilia so Jill can immediately QC Keller- Jill had Dr's appt for new baby today-tomorrow going to Keller.**
- Check with William: done

- FDA training
- Should HOU stop enrolling, ask William, please done-and done

- Put a plan in place to schedule weekly touchpoints with your PI's my SOM"s do this, for Plano and Houston. Alma does Burleson/I do Dallas/Arlington.
- Talk with JP done see the email.
  - What did she mean that "Ventavia is going to get what's coming to them"? she stated never said this
    - Let him know how concerned Dr. B is about that Dr B informed and see my email
  - Go over Peppler's concerns-comments about being unhappy, unsupported, etc. Peppler email reviewed with Jennifer.
  - Go over professionalism, growth, examples that have been given done- are we writing her up via verbal? Written? All three issues together? Or separately?
  - Have KB as a witness and make sure this convo is all documented and sent to us so we can make an informed decision (write up vs termination) done

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

VRG VENTAVIA RESEARCH GROUP PLATINUM RESEARCH NETWORK
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 9:19 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

www.ventaviaresearch.com

PLATINUM RESEARCH NETWORK

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 16, 2020 5:13 PM
To: Brook Jackson <bjackson@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Mercedes

- Get references for Tiara Done- she sent me three from Covance of people in three different positions (which is where all her experience is from)
  - I left a message for 2
  - Talked to the third one and she gave a glowing review. She said Tiara was the first non-RN to have an Operations Manager role. Covance at one point only allowed RNs as Operations Managers but when they opened it up to other, Tiara was the first to be promoted and to the Operations Manager of the morning shift which is the busiest shifts
  - I will try the other two again tomorrow if they don't call back tonight.
  - If good, then get a call with Medix

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

SILVER
CLINICAL RESEARCH CO-ORDINATOR

From: Brook Jackson <bjackson@ventaviaresearch.com>
Sent: Wednesday, September 16, 2020 4:01 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>
Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

Απολογιεσ μψ ρεσπονσεσ αρε νοτ ιν □ρεδ□; ωορκινγ φρομ πηονε το χομπλετε τηισ τοδαψ. Χομπυτερ ισσυεσ αγιν. Ωορκινγ ωιτη ϑερρεδ. Τηανκσ!

☐ Make sure Keller and FW have the Firecrest amendment 6 training completed by this morning - Almost there - will be done before EOB
☐ Speak to Jaz and have her go to Chrystal about communication with calling pts - Pending
☐ Speak to Jen Vasilio about overseeing Chrystal - Pending
☐ Continue to monitor recruitment efforts for FW and KEL-COVID - ongoing

On Sep 16, 2020, at 8:54 AM, Olivia Ray <oliviaray@ventaviaresearch.com> wrote:

Olivia Ray <image002.png>
Managing Member, Executive Director

JSN0397

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image003.png>

www.ventaviaresearch.com

<image004.png>

<image007.png>

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 4:50 PM
To: Brook Jackson <bjackson@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Mercedes

- Check with Kate on Amend. 6 ICF Confirmed all sites have this and have implemented it
- Give directive to sites and recruiters if we can start enrolling 16 and 17 yr olds- all sites know but will send a email so it's in writing
    - ICF IRB approved and received by sites received
    - Amend 6 firecrest training completed- notified sites to complete, protocol sent through Complion for signing off for training
- Follow up with reg person about hours and schedule – pending response

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image011.png>
<image014.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image015.jpg>

From: Brook Jackson <bjackson@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 4:38 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie/Brook

- Keep a close eye on Katie/Keller's enrollment numbers, she needs to continue to try and schedule the full 60 for the week. If she's having a challenge with less CRC's, she needs to loop us in before Chrystal decides to stop scheduling patients. We are currently at 42 scheduled for the week. We have open appt times each day that Lanie is working to fill, including a quick Saturday clinic from 7:30-8:45. Dr. Fuller wanted to be done with clinic on Sat. by 9:15.
- Work with Chrystal this week to get numbers up, check on CC list for 16 and 17 yr olds (or waiting list?) WORKING ON
- Focus on the recruitment this week for FW and KEL (Covid) – KEL is working on 2nd attempt emails, but have completed ThreeWire 2nd attempt calls; Lanie is also making calls right now to confirm 16Sep appts. For those she is able to reach she is asking if they have any potential referrals including those 16+.
- Help with Alma exit plan - MARNIE

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 4:05 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie/Brook

- Keep a close eye on Katie/Keller's enrollment numbers, she needs to continue to try and schedule the full 60 for the week. If she's having a challenge with less CRC's, she needs to loop us in before Chrystal decides to stop scheduling patients. BROOK
- Work with Chrystal this week to get numbers up, check on CC list for 16 and 17 yr olds (or waiting list?) WORKING ON

- Focus on the recruitment this week for FW and KEL (Covid) WORKING ON
- Help with Alma exit plan- TALKING TO ALMA NOW- she's coming down to the conference room to discuss options

Pending from yesterday:

- Get with Angela about adding onboarding newhire for the next two weeks, OT approved if needed (submit to Marnie or Mer for approval??) – DONE- Angela is going to send me a list of all the tasks she's working on and in the meantime, meeting with Katie, I belive tomorrow, to discuss what Katie needs her to do. Angela is willing to help but worried that she's going to drop the ball on all her other responsibilities, FYI. I told her not to worry about this, that we understand it will pull her from other duties.

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 9:31 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image003.png>
www.ventaviaresearch.com
<image004.png>

<image017.png>

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Monday, September 14, 2020 9:31 PM
To: Brook Jackson <bjackson@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie

Can you please get with Angela first thing (after our call in the morning) about taking over onboarding from Katie B?

We have Ruth and Jessica Mendez that need to be onboarded and they need to get moving quickly. I have multiple calls set up tomorrow so I need you to call Angela and get with her on this.

I think she has been working some with Katie on onboarding, so it should be a quick/smooth transition.

Regards,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image011.png>
<image014.png>
https://www.ventaviaresearch.com/   *http://www.platinum-research.net/*

<image015.jpg>

From: Brook Jackson <bjackson@ventaviaresearch.com>
Sent: Monday, September 14, 2020 4:03 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Marnie/Brook
14Sep2020

Can you have J. Valo work in GRA on Wednesday – DONE
Get with Katie Buchanan to add J.Valo to timeco – DONE; Marnie sent email to Katie Buchanan this am.
Jailyn-help email, make sure it was dealt with (with Jen Vasilo), please get Jailyn in a better place (documented games plan to get things distributed) – Per Jen V., they discussed action plan that will be documented in writing. Email pending from Jen V.
Let sites know to reach out to James/Burt when they need help filing so they can knock it out – Done.
Reach out to Jen Vasilo about Jerred's load and let him know about Katie Buchanan pulling him to work with her (newsletter, bamboo HR/timekeeping system, etc.) - DONE
Identify a scanner – DONE
Get with Angela about adding onboarding newhire for the next two weeks, OT approved if needed (submit to Marnie or Mer for approval??) - pending
Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week –** In progress

---

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, September 14, 2020 1:04 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

9/14
Kandy

- Let sites know to reach out to James/Burt when they need help filing so they can knock it out email sent.
- Identify a scanner. I sent out an email to Ventavia.
- Get Univision ad ran today. I have sent email, working on getting out by Wed/Thursday.
- Get in touch with Christine to see if Lizatte can call Syan Rhodes about a follow-up story, and then all other HOU sites done
- Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week done**
- Talk to Christine about extending Tony's contract if he can done and extended till he gets an offer or no longer needed.
- Talk to Becca about staying in ARL for right now, and have her go to Dallas one day this week to QC done-she has a 2 weeks sch for Arlington, adding QC for Dallas in there as well. She is out next week for a couple of PTO days.

9/11
Kandy

- Precillia review to Mer Jill sent the revision
- Tell Christine to make second interview rounds and narrow it down done on 9/11 via phone

JSN0402

- Talk to Mark about helping with reg done on 9/11 via phone and email.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image011.png>
<image014.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, September 14, 2020 9:32 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image003.png>

www.ventaviaresearch.com <image004.png>

<image017.png>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Saturday, September 12, 2020 1:18 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

I'm not sure if this was ever answered, but there was a question about the PM role being a promotion for JV. It is not. I do understand there are some SOMs going into this role, but it's a new position...and it's not a promotion for JV. It's still a lateral move for her. She was managing MRSV medical records and now she's managing more (old studies).

We can discuss further on Monday, if need be.

Kristi Raney
Managing Member,
Executive Director

<image018.jpg>

Ventavia Research Group
1307 8th Avenue, suite 202
Fort Worth. TX 76104
t: 214.208.0390
e: kristiraney@ventaviaresearch.com

www.ventaviaresearch.com/
www.platinum-research.net

On Sep 10, 2020, at 4:01 PM, Kandy Downs <kdowns@ventaviaresearch.com> wrote:

Kandy

- QC MAT RSV charts in FW They were already done-
- Continue reviewing resumes and will forward those recently reviewed to Kristi/Mercedes already forwarded

Completed onboarding/New Hire training with Becca S and Brook. Worked on emails/ Review for Jennifer completed.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, September 10, 2020 10:57 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Sorry, with attachment.

Regards,
Marnie

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, September 10, 2020 10:16 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Call notes from this morning.

Regards,
Marnie

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 9, 2020 9:16 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Call notes from this morning.

Brook- We all have alarms set at 4:00 on our phones as a reminder to send a follow-up on our to-do list from the morning call. We copy and paste our section of to-do in this email chain and in red next to the time we write out the outcome.

I put items under you/Marnie today. Please shadow her on all her action items and if there are any you can take over (after introducing yourself to those involved in the action item) you can do that as well.

All responses stay in this email chain so it's easy to reference from one day to the next.

Regards,

Mercedes

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>

<image002.png>
https://www.ventaviaresearch.com/ http://www.platinum-research.net/

<image003.jpg>

From: Mercedes Livingston
Sent: Tuesday, September 8, 2020 6:30 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Kandy

To confirm, are you saying you already did Cristina's review with her? If not, please don't I want to review it first (I'm working through emails). Also, you will want to have Katie B on the phone when you do the review with her. We want to have a witness on all reviews/disciplinary/coaching sessions.

Regards,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ http://www.platinum-research.net/

<image003.jpg>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 5:11 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Kandy

- Work on Univision thing-have spoken to 3 different people that are working up numbers and such. The attachment that I got was for COMCAST- and is a joke. So working with really Univision. Will send emails as they come for approval and cost
- Get reviews to Mercedes-send Cristina's and completed today. Almost finished with Jennifer P having Becca help me since we both have been working with her.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 8:23 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Olivia Ray <image004.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com <image006.png>

<image007.png>

From: Olivia Ray
Sent: Friday, September 4, 2020 12:07 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Sorry I forgot to send this out this morning!

Olivia Ray <image004.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com <image006.png>

<image007.png>

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Thursday, September 3, 2020 4:47 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Mercedes

- Get Angela ready to go remote next week- done
- Get resume from Kati Dykes to call and interview- LM, phone went straight to VM

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Mercedes Livingston
Sent: Thursday, September 3, 2020 4:43 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Yes, Becca trained her on it this morning. JP followed up in a text to me confirming.

Regards,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Thursday, September 3, 2020 4:15 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items-Kandy

Mer, was your last email addressing this...

Pending visits in CC in ARL the last couple of days Sent a request to Jennifer to either complete them or move them over. I can’t move them when I don’t know what is going on with them. Also, need Kandy to be on top of this with Jennifer.

Can Becca help with this? Maybe she can 1) help get it caught up 2) make sure JP understands and doesn't have any questions

Just want to make sure this got addressed (either Becca helping or JP getting it done).

Thanks,

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202

Fort Worth, TX 76104

817-348-0228 Office

817-394-1901 eFax

214-208-0390 Cell

<image008.png>
<image009.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 9:18 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Jennifer actually called me when she got my email. She hasn't been using the check-in check out page to look at these. So, I showed her where I was looking and now she knows. She is going to call me tomorrow when she is ready to complete her diary check visits so I can show her how to do them from the check-in check-out page.

Thanks,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 5:10 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items-Kandy

Pending visits in CC in ARL the last couple of days Sent a request to Jennifer to either complete them or move them over. I can't move them when I don't know what is going on with them. Also, need Kandy to be on top of this with Jennifer.

Can Becca help with this? Maybe she can 1) help get it caught up 2) make sure JP understands and doesn't have any questions

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202

Fort Worth, TX 76104

817-348-0228 Office

817-394-1901 eFax

214-208-0390 Cell

<image010.png>
<image011.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 5:03 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Mercedes

- Talk with William about his recommendations for QC employees requested from William. Directed him to do the first interview and send to me for second interviews
- Log into Firecrest to see if we have a radio ad already approved by Pfizer Not in Firecrest, pending reply from Arturo
- Talk to Haily, Elyza, and Jessica today so we can make a decision on Erin LM for Elyza and Jessica. Haily doesn't have any experience regarding Clinical Research that would apply to step into a CRC role at any site.
- Oversee the Inv onboarding email ongoing
- Pending visits in CC in ARL the last couple of days Sent a request to Jennifer to either complete them or move them over. I can't move them when I don't know what is going on with them. Also, need Kandy to be on top of this with Jennifer.
- Send an email chain to get status update at end of each day, how many they got to, etc. Any glaring findings? Set an alarm. Email sent

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group

1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/   *http://www.platinum-research.net/*

<image003.jpg>

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, September 2, 2020 9:29 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Olivia Ray
Managing Member, Executive Director

<image004.png>

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

www.ventaviaresearch.com

<image005.png>

<image006.png>

<image007.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Tuesday, September 1, 2020 5:02 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>
Subject: FW: Daily Status Calls Updates and Action Items-Kandy

Sorry only sent to Olivia

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Kandy Downs
Sent: Tuesday, September 1, 2020 5:01 PM
To: 'Olivia Ray' <oliviaray@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items-Kandy

Kandy
- Look at resumes for CRC's for almost all sites done- see the attached resumes I reviewed that I thought would be good fits. There were no notes with these.

I have tagged them all via Indeed message to see if they are still interested in the positions before we start calling them.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, September 1, 2020 8:53 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image004.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com
<image006.png>

<image007.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, August 31, 2020 3:56 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

- Have Cordy do the first vaccine on the phone with her Done. And rechecked when onsite.
- Dallas-IRB documentation emails Shannon informed and Precilia to work with Shannon
- Keller phlebotomist email-follow up with Katie (Cara Lopez-rate) Katie reminded, to contact her.
- Let Olivia know if we need to activate HOU ad tonight
- Help with Katie B email re: investigators work in progress- to be honest, I have only reached out to Dallas. Been busy with Keller.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 31, 2020 8:46 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray
<image004.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com
<image006.png>

<image007.png>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Friday, August 28, 2020 10:21 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items- Kandy

I agree with what Olivia said. I actually feel like this was brought up a few weeks ago...that she had no training and has very little oversight bc she is the unblinded. I feel like that's when Kandy went over there a week or so ago and caught the Becca situation...but I thought part of our discussion was that she had no oversite and could be screwing up and no one know.

Maybe I thought this all though...and never actually said it out loud...idk.

So yeah, let's see who we could possibly get over there with her to start helping out on Monday. Otherwise, something bad is going to happen with her.

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202

Fort Worth, TX 76104

817-348-0228 Office

817-394-1901 eFax

214-208-0390 Cell

<image012.png>
<image013.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Friday, August 28, 2020 10:11 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I spoke with Kandy and she is heading to Kel this afternoon to help Cordy get items corrected and clarified on her logs and get with the unblinded CRA to address any items she has.

Kandy, please let us know how this afternoon goes. As it stands now, I'm not comfortable with Cordy being the only unblinded vaccinator for this trial.

- Is there an experienced unblinded for this trial that can go work alongside her starting Monday, until we feel comfortable she knows what she is doing?

Thanks,

Olivia Ray
Managing Member, Executive Director

<image014.png>

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com

<image006.png>

<image015.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, August 28, 2020 9:58 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Morning;

See in purple my FUL to your blue. LOL

I also want you both to be aware that we (Keller site) unblinded received an email from the blinded CRA-there are a lot of concerns. I will try to address via remote if I can't, then I will have to go to Keller today to review and discuss with Cordy. It looks like CRA has tried to work with Cordy but not getting a resolution. But I will contact Cordy this morning, and I will see what I can do from Arlington.

See below.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

JSN0421

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Friday, August 28, 2020 7:54 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I know we aren't having a call this morning due to Mer seeing a pt and me on the PSSV, but I wanted to address a couple of things. See in blue:

- Reach out to KB in KEL about EDC entry email sent to Mercedes- EDC good/Complion need helps-Katie B informed to have uploaded, and we can have Jerred remote file for them. Is Keller planning on working tomorrow to get Complion caught up? Unless I am missing something, this needs to be caught up before the week is over. When I spoke with Katie B yesterday, she stated that they were going to get uploaded by today. And have EDC updated daily I will reach back out today and see where they are.

- Reach out to Christine, Lizatte, Jill re new roles Discussed;

  Jill-location? Remote? Then maybe some travel sch. Salary increase? Or the same? Interested-timeframe of a switch? Kandy, see in the email I sent yesterday that answered the remote and onsite question. I copied and pasted below in case you need to touch base with Jill again with some of that information. Salary—we will get back to you on that. Timeframe—I feel like that depends on when Shannon and Christina are better trained and don't need PLA to lean on. I would suggest telling Jill in the meantime, to learn everything maternal while working in PLA, and how we have set it up this year. So she knows how to get the sites better prepared when GSK starts (pre-screening docs, etc.) Perfect.

  Lizatte- Is excited, and Christine is yes, this is so Lizatte. Both onboard with this laterally move.-? We will get back to you about lateral move vs. salary increase. I will need to schedule a time with Lizatte to train

her and go over her role. I will wait and do that once Pfizer enrollment has stopped—unless you think they can enroll without her? Right now, with 3 new hires being trained, Lizatte is needed. I am thinking the end of the COVID study.

Study Manager/Project Manager/Protocol Facilitator Role (whatever we decide) (How to present this role to Jill and Dana—we can hold off on Becca)

- Brand new role created for the company to ensure we are setting everyone up for success
- Mainly remote, with onsite visits during first days of enrollment to ensure accuracy of everything being followed
- Working in conjunction with the RD's to make each site/study successful
- Need for experienced CRC's who have been with VRG for a while who know our processes
- Critical position where planning, details, and follow-through are extremely important
- HUGE amount of trust will be placed in this person/position

Reviewed this with Jill-

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com <image006.png>

<image017.png>

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 4:51 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Mercedes

- Reach out to Erin re: medical records- According to Marnie's email this morning, she has already had this discussion with Erin, Kati D, and Jennifer V

- Go through Kate's email and reach out to Becca about source (Pfizer Mat RSV and COVID) Done. Kate sent Becca what she has (rough draft docs) and Becca said she would have RSV and COVID done by EOB tomorrow

- Kate-OT approved, talk to her about training William- Kate doesn't think she wants PTO. Her weekends are her time to decompress and destress for the anxiety of her weeks. I did instruct her to get with William (since source came off her and we are holding off on GSK reg packets) and Kate it to get with William and spend about an hour trying to loop him in.

- Final interview/vet Erin McLeod, approval to hire for FW, 57k I talked to Erin and I liked her. Seems eager to learn and very smart. Her research experience is in non-industry trials (derm studies on makeup, lotion, hand soaps, baby wipes, et) so she would have a transition period to learning FDA regulated trials. I'm going to try and get to a few more that Jennifer has done first rounds on and then come back to her.

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell: 817.845.3824
Office: 817.348.0228
eFax: 817.394.1901
mercedeslivingston@ventaviaresearch.com

<image018.png>
www.ventaviaresearch.com

<image019.png>

<image002.png>
www.platinum-research.net

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 4:38 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Kandy
8/27

- Reach out to Christine, Lizatte, Jill re new roles Discussed;

    Jill-location? Remote? Then maybe some travel sch. Salary increase? Or the same? Interested-timeframe of a switch?

    Lizatte- Is excited, and Christine is yes, this is so Lizatte. Both onboard with this laterally move.-?

- Go to the sub-I mess of an email and handle Marnie's sites also so I tried, I will work on tomorrow. Needs more time than 1 day.
- Angi training for Pfizer mat RSV over the weekend done!
- Reach out to KB in KEL about EDC entry email sent to Mercedes- EDC good/Complion need helps-Katie B informed to have uploaded and we can have Jerred remote file for them.

8/26 missed couple yesterday

- Pending visits in CC-see Mer's email (DAL, ARL, HOU) was done yesterday.
- Call Kate and ask her to resubmit PSF for COVID-19 (from CC) ASAP I updated the form(learned how) and sent email Gabby. See the email (per Kate W help)
    - IRB approved autoimmune diseases, incl T1 diabetes (but this is incorrect and needs to be removed) removed- and #21 updated since 28 days have to be applied to this exclusion.
- Work with Chrystal to figure out how to identify and contact any subjects we inadvertently PS failed bc of T1 diabetes and re-PS for scheduling Chrystal has a list- and Pam already slacked. 27 subjects on the DNQ for various reasons-only 1 DM. RA subject to confirm about Immune meds.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202

Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 8:34 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Study Manager/Project Manager/Protocol Facilitator Role (whatever we decide) (How to present this role to Jill and Dana—we can hold off on Becca)

- Brand new role created for the company to ensure we are setting everyone up for success
- Mainly remote, with onsite visits during first days of enrollment to ensure accuracy of everything being followed
- Working in conjunction with the RD's to make each site/study successful
- Need for experienced CRC's who have been with VRG for a while who know our processes
- Critical position where planning, details, and follow-through are extremely important
- HUGE amount of trust will be placed in this person/position

Olivia Ray <image020.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com <image006.png>

<image015.png>

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, August 27, 2020 7:41 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

My apologies, I had this pulled up to send but didn't send. I'm out of the office today and tomorrow but will be available by phone if needed.

I'll send you a f/u on the discussions I had with staff changes as well.

Marnie

- Pending visits in CC-see Mer's email (DAL, ARL, HOU)- Kandy's sites, but noted and will f/u also if needed.
- Check on unblinded situation for KEL- Pending Jill/Precilia's training on Firecrest- both will help as back-up. Cordy will continue to use Gina as sign-off.
- Work with Jen Vascilio about Saturday clinic for covid-19 DONE- Jen is working on and will send f/u today.
- Need to make KEL and FW understand that in order to get the $500 stipend, they need to work whatever it takes (late nights and Sat clinics) to get close to their enrollment goal each week DONE

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 26, 2020 8:58 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com

<image006.png>

<image007.png>

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Tuesday, August 25, 2020 4:46 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Mercedes

- Call Deedra and offer ARL- This is pending the presentation tomorrow, I believe
- Get with Marnie and decide who needs to get added to Keller PSSV- I will be on the call

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

<image003.jpg>

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, August 25, 2020 9:03 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray
Managing Member, Executive Director

<image021.png>

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

www.ventaviaresearch.com

<image005.png>

<image006.png>

<image022.png>

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Monday, August 24, 2020 11:46 PM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I apologize for the delay on this, we were short-handed today in FW and then I had our PSSV at 3, so I wasn't able to get to this on time.

- Check on PSSV time today for Novavax (make sure to mention access to minorities and healthcare workers), grab JV or Angela for any VRG specific questions **DONE**
- Offer the $500 weekly stipend to all FW clinic employees willing to work OT/Sat clinics to get these 60 in, manager needs to collect the employees' names and submit these stipends to payroll at each run, cc Kristi, Olivia, Mercedes, so payroll knows its legit **DONE**- communication sent, pending feedback.
- Thea-speak to her about urgent matters, she should have told us RIGHT way, we could have had all weekend to schedule and plan for this week. This is a HUGE deal. Verbal warning. Now we might have lost 20 pts for this week. This was hundreds of thousands of dollars on the line. If she emailed it on Friday, the email needs to be forwarded to us. I will send an email out, as directed below. I explained to Thea how critical this is and she stated she understood and will be sure to alert leadership immediately. She said she was following the chain of command by alerting Dana and then myself, but I reminded her to reference the Ops Manual for important communications- I pulled it out and we went over it together. **SEE ATTACHED** email from Arturo- he sent this last night.
- Get Janssen game plan going for season 2 participants (49 pts, 3 hours visits, starting Sep 7th?) **WORKING ON**- today I completed the updates for the IBC items they needed to be completed that were delayed- initially sent to Michelle. This took me more time than expected since I didn't have anything at my fingertips, but got it all figured out.
- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion **DONE**
- Pending visits in CC Aug 20th **DONE-** There are tons for FW today that didn't get completed- Dana stated that she instructed Thea and April to make sure they got done today because she was OOO today, but I just checked and none of them were done. Dana will get this done first thing in the morning. We only had 4 CRCs today and saw 27 patients in total.

Regards,
Marnie

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Monday, August 24, 2020 12:42 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items- Kandy

Marnie,

Thanks for digging in on this. I still don't think it's okay for Thea to hear that kind of SUPER important information and not relay it to leadership immediately.

I really expect this will never happen again. I would also appreciate you sending out an email to all sites and let them know that if a situation like this ever happens (increase in enrollment cap lifted) that they immediately notify leadership.

Thanks,

Kristi

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202

Fort Worth, TX 76104

817-348-0228 Office

817-394-1901 eFax

214-208-0390 Cell

<image012.png>
<image013.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Monday, August 24, 2020 12:22 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

I wanted to touch base about this issue below with Thea- she said she hasn't received a confirmation email from Arturo yet, it was only a phone call Friday and he said we could "possibly" enroll 60- she left him a voicemail to follow-up with us ASAP by email.

Marnie

- Check on PSSV time today for Novavax (make sure to mention access to minorities and healthcare workers), grab JV or Angela for any VRG specific questions

- Offer the $500 weekly stipend to all FW clinic employees willing to work OT/Sat clinics to get these 60 in, manager needs to collect the employees' names and submit these stipends to payroll at each run, cc Kristi, Olivia, Mercedes, so payroll knows its legit

- Thea-speak to her about urgent matters, she should have told us RIGHT way, we could have had all weekend to schedule and plan for this week. This is a HUGE deal. Verbal warning. Now we might have lost 20 pts for this week. This was hundreds of thousands of dollars on the line. If she emailed it on Friday, the email needs to be forwarded to us.

- Get Janssen game plan going for season 2 participants (49 pts, 3 hours visits, starting Sep 7th?)

- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion

Pending visits in CC Aug 20th

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 24, 2020 9:23 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772

e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com

<image006.png>

<image023.png>

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Monday, August 24, 2020 5:52 AM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items- Kandy

I'm a little concerned about the "restructure" statement. I don't feel HOU needs someone coming in and restructuring them. And I'm wondering how she even came up with that when she hasn't seen anything or how they function, etc.

I'm not sure I'm sold on this one. And she's too expensive.

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202

Fort Worth, TX 76104

817-348-0228 Office

817-394-1901 eFax

214-208-0390 Cell

<image024.png>
<image013.png>
https://www.ventaviaresearch.com/   *http://www.platinum-research.net/*

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Friday, August 21, 2020 4:53 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

- Call HOU RD to see if interested in contract QC position, get rate, ask about travel to DFW if she were to get the RD position Reached out, and talked with Judy. She is at 60$ here, which is still $125K yearly. She is not interested in contract work-but will take an RD position with Houston and a Dallas(she has family up in the area) My only concern is that she and same Jennifer V stated was she would want to remake the system in Houston- instead of working with the status quo and making improvements she would want to restructure. But otherwise, she is great to talk with interaction was great. I called Judy to try and get a feel for her. I spoke with Kandy and got some feedback from her call and I understand she isn't wanting a contract QC position. I would like to talk to her and get a feel for her. I left a voicemail and followed up with an email to try and schedule a time to talk either Monday or Tuesday- Mer
- Get HOU to create a schedule for COVID enrollment I have asked Christine, they a lot of enrollment this afternoon, she is going to work on getting to us by tomorrow morning before 8 am.
- Create a site plan to recognize holes pending on with Marnie.

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell: 817.845.3824
Office: 817.348.0228
eFax: 817.394.1901
mercedeslivingston@ventaviaresearch.com

<image018.png>
www.ventaviaresearch.com

<image019.png>

<image002.png>
www.platinum-research.net

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, August 20, 2020 5:25 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Kandy

- Call HOU RD to see if interested in contract QC position, get rate, ask about travel to DFW if she were to get the RD position Reached out, and talked with Judy. She is at 60$ here, which is still $125K yearly. She is not interested in contract work-but will take an RD position with Houston and a Dallas(she has family up in the area) My only concern is that she and same Jennifer V stated was she would want to remake the system in Houston- instead of working with the status quo and making improvements she would want to restructure. But otherwise, she is great to talk with interaction was great.
- Get HOU to create a schedule for COVID enrollment I have asked Christine, they a lot of enrollment this afternoon, she is going to work on getting to us by tomorrow morning before 8 am.
- Create a site plan to recognize holes pending on with Marnie.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104

Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, August 20, 2020 9:06 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com <image006.png>

<image025.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 5:11 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Kandy

- Find an employee to hire to upload Complion for COVID-19 Christine husband offered/accepted, sending information to Katie for background and onboarding fast track (LOL Katie)
- Find or delegate someone to find a high-speed/high volume scanner to purchase for sites that need it Already talking with Jerred, pending more research should have more in the morning
- Finish write up and send to everyone for review Done-send at 5pm.
- Get with HOU regarding 5 pending visits in CC from 8/17 Christine aware, and will check in at 530pm

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 2:27 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Sorry about that.

Olivia Ray
Managing Member, Executive Director
<image016.png>

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com

<image006.png>

<image026.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 2:19 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

So this attachment is for yesterday. Do we have today?

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 19, 2020 9:09 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com <image006.png>

<image025.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Tuesday, August 18, 2020 5:01 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items- Kandy

- Talk to your COVID sites. Yes, this was done with Houston.
    - As soon as they have a no show, call the recruiter and tell them to fill the spot

  - Schedule 20 Mon and 20 Tues, and 8 pts for Wed (in case recruitment cannot replace N/S's on Mon/Tues) If we hit our 40 by Tues, then move Wed's 8 pts to the following week. Houston just increased to 80 per phone call
  - Pull up CC and account how many are short Rudie is working on adding patients

- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance. Houston at 455pm had a total of 27- multiple ediaries, Visits 1 that are occurring, will have done by EOD-still enrolling COVID subjects

  Burleson had 3 spoke with Alma

  Dallas had 1-canceled enrollment from today.

- Talk to maternal calls, on-call phones need to be with them at all times. Mom's are starting to deliver. Patients, staff, doctors are to ONLY call on-call phone. Not personal phones! This was relayed via phone call, and an email sent.
- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit. So, I am still confused about what exactly this would mean to me directly. So I am the Regional Director-would I lose my title? Or would the Support specialist title be under me, and I would be relabeled?

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, August 18, 2020 11:21 AM

To: Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Mercedes, please make sure you address Kandy's questions below from her previous email. And I HOPE the system doesn't prevent us from making up numbers from last week and then we don't run into this issue again, starting next week!

So, confirming that Keller needs only to get to 40 this week, and last 14 from last week, we can't enroll?

Same in Houston the 9 we thought to makeup, we have lost. So questions will the system prevent them from enrolling if they go over?

On the IP, so since the placebo is approx. 30, and the drug is approx. 20- - so you are stating 15 to 20 mins for both for IP prep time and then giving?

I just want to make sure I have the right mindset here.

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com <image006.png>

<image025.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, August 17, 2020 4:56 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>

Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

So, confirming that Keller needs only to get to 40 this week, and last 14 from last week, we can't enroll?

Same in Houston the 9 we thought to makeup, we have lost. So questions will the system prevent them from enrolling if they go over?

On the IP, so since the placebo is approx. 30, and the drug is approx. 20- - so you are stating 15 to 20 mins for both for IP prep time and then giving?

I just want to make sure I have the right mindset here.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Monday, August 17, 2020 4:27 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

847/2020 Action Items
Mercedes

- Confirm with Pfizer about what constitutes a week, can we get a head start on a Friday (as long as we don't go over 40 the following week), what is the window of IP
  - A week is Monday- Sunday
  - They are going to start capping each site for the next few weeks to randomizing 40 patients a week
  - This means, if we are short one week and only enroll 35 pts, we **CANNOT MAKE THOSE 5 UP THE FOLLOWING WEEK!** We lose those 5 pts.
  - We will start receiving larger shipments but we **CANNOT** enroll over 40 pts a week. The larger shipments are for the V1 and V2s that will start coming in.
  - It may be Sep before they look at raising anyone's drug supply or allowing for overage.
- Confirm with Pfizer that time IP needs to stay out and give proper directive to Marnie and Kandy, so they can let their unblinded staff know
  - This is what is in the IP manual in regards to thawing:
    - 8.4. In-Use Shelf Life and Storage Requirements for BNT162 Vaccine and Placebo Vials Vials of BNT162 Vaccine Concentrate Solution for Injection, 0.5 mg/mL must be stored in the freezer between -80 and -60ºC (-112 to -76ºF), protected from light and kept in the original packaging until ready for use in dose preparation. Allow all vials to thaw at room temperature (no more than 25 °C/ 77 °F) for **approximately 20 minutes** prior to dose preparation. When the contents of the vial are completely thawed, gently invert 5 times to mix thoroughly. Do not shake. If unused vials are left at room temperature for more than 2 hours they should be discarded. Minimize exposure of BNT162 Vaccine vials and prepared dosing solutions to room light during storage. Avoid exposure to direct sunlight and ultraviolet light. Dosing solutions can be prepared and handled in normal room light conditions. Placebo vials of 0.9% Sodium Chloride, USP (10 mL/vial) shall be stored at 20 to 25 °C (68 to 77 °F).
  - This is in regards to Placebo (pg 35):
    - In order to maintain the study blind, the label on the final prepared active and placebo dosing syringes must have a blinded product name (e.g. BNT162 Vaccine 10 mcg, 20 mcg, 30 mcg, or Placebo) as well as the same expiry date and time.
    - If preparing the placebo dose, please wait at least 30 minutes after dose preparation before delivering the final dosing syringe to the location of administration in order to maintain the study blind.

- Sponsor-provided occluding label must be applied to all prepared active and placebo dosing syringes to maintain the study blind. •
- A confirmation of study blind statement must be documented in the participant's source documents (see below) • Document all steps performed as indicated in the Preparation Record (Appendix 5, 6, or 7).

o So what it is saying is **study drug** should thaw for approximately 20 min, maybe more like 15 if being warmed in hands, etc. But, we can't just go and draw up Placebo and give it to the pt, if would be obviously. So, I think each unblinded needs to be made aware that the thawing time for the study drug is **APPROXIMATELY** 20 min. I would encourage them to get it to the 15 ish mark, and then draw up when it's totally thaw and then draw up placebo in around the same amount of time. What I don't want, is the study drug sitting in the room for 30 minutes with nothing happening. It doesn't say 30.

o If unblinded takes the drug out of the freezer and holds it in their hand (the vial) while filling out paperwork, etc. it will likely be thawed around 15 minutes and that shaves considerable amount of time off our pt wait time.

o I sent an email to Arturo with my thoughts/suggestions on the approximate language and I'm awaiting a written response from him before sending direction to the sites.

- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia – Done
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia- Done
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.- I just checked CC (8/17/2020 3:57) and there are only two pts. Pending in CC from 8/3-8/14. One in Dallas and one in Arlington.
- Get Burt's help to get the laptops set up in FW- Done

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

<image001.png>

<image002.png>
https://www.ventaviaresearch.com/ http://www.platinum-research.net/

<image003.jpg>

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 17, 2020 8:57 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Action items for today.

Olivia Ray <image027.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com <image006.png>

<image028.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Monday, August 17, 2020 6:32 AM
To: Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Kristi
Spoke with Christine last night
Will make up our 9 from last week today.
Then 20 to 24 set for tomorrow and then 20 to 24 set for Thursday. If we are shirt then weekly 40 by Thursday. The Saturday will be used to meet our weekly numbers.

Thanks for taking my call. And Houston will be on track after today.

Warm regards,

Email sent via cell phone

Lovica "Kandy" Downs
Regional Director/RMA, BBA, CCRC

<image029.jpg>

Ventavia Research Group
1307 8th Ave, Suite 202
Fort Worth. TX 76104
t: 817.269.5997
e: kdowns@ventaviaresearch.com

www.ventaviaresearch.com/
www.platinum-research.net

-------- Original message --------
From: Kristi Raney <kristiraney@ventaviaresearch.com>
Date: 8/15/20 13:18 (GMT-06:00)
To: Kandy Downs <kdowns@ventaviaresearch.com>, Olivia Ray <oliviaray@ventaviaresearch.com>, Marnie Fisher <mfisher@ventaviaresearch.com>, Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>, Katie Buchanan <kbuchanan@ventaviaresearch.com>
Subject: Re: Daily Status Calls Updates and Action Items

Kandy,

I was just looking in CC. It appears HOU only has 31 patients that randomized from last week. Why did they not hit their 40?

Next week, they have

M: 1
T: 21
W: 1
Th: 20
F: 0

I understand, Kandy, that Tran wants to see the patients at certain times he closes his practice, but this isn't working for us. First of all, they're not hitting their numbers. Second of all, when Pfizer increases the 40 doses, it will be hard for them to give them to HOU if they aren't hitting their 40 and they aren't doing it quickly.

If we need to consider utilizing our subI's (Garza or Kat) then that's what we have to do.

But I really needed my direction to be followed from the beginning. I understand that Tran had a different plan due to his patients and practice, but we can't allow that kind of stuff to impact a high-enrolling study. I know you brought this up on our call last week, but I didn't fully grasp the impact. In the future, if you need to detour off of my recruitment guidance, I need you to seek approval first before you agree or put anything into action. You brought the detour up really quickly on our call and it was already in place when you told me about it, so it was a little too late for me to say no (though I now realize I should have). The direction was to see the 40 patients within the first 2.5 days...so that when Pfizer did increase their cap, we'd be the first ones approved for additional druge (and I did clearly explain my strategy and the rationale behind it when I gave my direction). And now, Pfizer is planning to increase their drug and HOU didn't hit their 40 in the first week. Honestly, that's unacceptable. I need you to figure out how 9 patients will be randomized on Monday.

Recruitment is extremely strategic and it's not something that can have decisions made on the fly. We have had so many people give it a go...and the only other person who has been successful at it, is Mercedes (and obviously, she has no time for that right now). Katie Buchanan will be taking it over (training is starting this week) and the same guidance follows for her too. If she gives recruitment instruction, then no changes can be made unless approval is given by her (until she is trained, it's me).

Let me know if you have any questions.

Thanks,

Kristi

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202

Fort Worth, TX 76104

817-348-0228 Office

817-394-1901 eFax

214-208-0390 Cell

<image030.png>
<image031.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, August 14, 2020 4:13 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

- Make sure HOU has same Complion plan in place as KEL and FW Houston is doing the same
  - Initial and dating any blanks as everything might have already been uploaded. Houston is QCing before uploading
  - Have all sites give an update by EOB Houston to upload about 10 more.
  - Tomorrow needs to be worked to get everything caught up Houston can't there is a building shutdown.
- Offer OT to anyone who can come in and get things caught up on Sat offered to all my sites.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Friday, August 14, 2020 9:30 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com <image006.png>

<image026.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Thursday, August 13, 2020 4:04 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

See in Red. From today.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>
<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Thursday, August 13, 2020 9:32 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com <image006.png>

<image017.png>

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Wednesday, August 12, 2020 4:59 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Hello- here is my daily task.
Pending only the CAPA, been working on Houston enrollment.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com

<image001.png>

<image002.png>
https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Wednesday, August 12, 2020 8:56 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

Olivia Ray
Managing Member, Executive Director

<image016.png>

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

www.ventaviaresearch.com

<image005.png>
<image006.png>

<image017.png>

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, August 11, 2020 5:55 PM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

I did Kandy's in blue as well:

Marnie

- Cordy
  - Check-in on her, see if there is another unblinded that can replace her so she can get back to recruiting PENDING- need to figure out who we can use as a back-up (otherwise she's doing okay)
- Talk to Nika
  - Get Anne on the phones today, along with Alaina (do not pull them off the phones) DONE
  - Check on drug (arrived today)
  - Make sure they are knocking out new drug in 2.5 days (16/16/8) DONE
  - Make sure Katie is in Grapevine on Fri afternoon, so get help from someone else if needed DONE
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them (Alma, Becca, Kati D, etc.) DONE
  - Go over ediary issue/falsifying data, etc. DONE
- Talk to Becca
  - Help create the schedule for KEL COVID PENDING- I'LL CALL HER ON WAY HOME
- Talk to Dana
  - Go over Mer's email re: COVID scheduling DONE ON 8/10/20
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them DONE- discussed with Dana
  - Go over ediary issue/falsifying data, etc. DONE- Thea also verbally counseled for changing data and not noting late entry
- Chrystal
  - Tell her to change the visit time to 2 to 2.5 hours DONE on 8/10/20
  - She needs to train recruiters to start capturing race in CC DONE
- Talk to JV
  - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed PENDING- will try to call on way home
- Talk to your sites about capturing race in CC when a patient comes in PENDING- should we update the source documents?

Kandy

- Nikki-make sure unblinded for COVID (to free up Jailyn to see maternal pts), blinded for all maternal/pedi, eventual training on Medical Records DONE- I just talked to her myself and Kandy talked to Dana.
- Talk to Nadia (with Marnie)-can we get Nadia switched to onboarding/admin duties/take tasks over from Katie Buchanan for the next couple of months until Dana can take it back over. If she is, then please facilitate the process between KB and NM and the FW site to get this started. DONE- Kandy and I talked to Nadia together about everything (Linda issue, job function, etc.) She is eager to learn anything and everything, but is not sure she has time right now with all other duties. Kandy is trying to call Olivia to discuss an idea of Jazmine taking this on.
- Talk to Christine- DONE

- o About the Complion upload station- new admin, Maria
- o Go over ediary issue/falsifying data, etc. DONE
- Talk to your sites about capturing race in CC when a patient comes in PENDING

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Tuesday, August 11, 2020 9:10 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

See attached.

Olivia Ray <image016.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com <image006.png>

<image025.png>

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, August 11, 2020 7:41 AM
To: Olivia Ray <oliviaray@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Daily Status Calls Updates and Action Items

I missed this, Olivia, but I'll do this moving forward, thanks.

Marnie:

- Get resume over from Kati Dykes-possible CRC asst (DONE- Katie sent to Mercedes yesterday)
- Call Nika/Katie:
  - Anne needs to focus on scanning into Complion as much as possible this morning DONE- but tasks changed. Katie had Anne catching up the uploading of consents into eConsent and reviewing diaries. I took on scanning, but didn't get anywhere- still pending getting access to study in Complion. Kate apologized for the delay, she will get it done this morning.
  - Need to start scheduling starting Tues afternoon for new covid pts DONE
- Call FW:
  - Get a game plan in place to get Complion caught up in EOB today CALL DONE- but the task is PENDING
  - Move patients within their window to fit more COVID pts CALL DONE- but the task is PENDING. FW prefers to schedule as initially planned since appointments have already been made, for example, on Friday. However, FW confirms to schedule based on Mercedes new plan starting next week.
  - Let Dana know Mer needs to know when they have a pedi blood draw due to so many deviations, so she can go up and draw DONE- by Mercedes
- Call Jennifer Valo that she needs to be in FW the rest of the week DONE- will be in FW Wed and Friday and working on coverage for kids so she can be there Thursday
- Call Chrystal and:
  - Direct John to call for KEL DONE
  - Cordy cannot be responsible for KEL recruitment right now ACKNOWLEDGED- all parties know
  - Tell her OT is approved for nights and weekends so we can get spots filled WILL DO NOW
  - Let her know Shannon (anyone else), must call AND schedule DONE
  - If newbies have questions, put them on hold and ask a seasoned employee, bc everyone needs to be trained and, on the phones, as soon as they can DONE

Regards,
Marnie

From: Olivia Ray <oliviaray@ventaviaresearch.com>
Sent: Monday, August 10, 2020 10:16 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>

Subject: RE: Daily Status Calls Updates and Action Items
Importance: High

Let's add another layer to this so we can make sure we are all staying on top of our lists:

- Set an alarm on your phone for 4pm
- Copy and paste your action items in an email reply back to this chain and state status (DONE or Pending-update as to why)

Example (and this is actually mine for today):

- Hiring-Indeed Ads-Tweak to add the following
  - HOU-CRC, FW-CRC, KEL-2 CRC, 3-5 years' experience-DONE

This is to create a new habit of double-checking if you complete your items by EOB. If not, then you are learning to pull your resources to help get it done before the next morning's call.

Thanks,

Olivia Ray <image032.png>
Managing Member, Executive Director

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>
www.ventaviaresearch.com <image006.png>

<image026.png>

From: Olivia Ray
Sent: Monday, August 10, 2020 9:00 AM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Kristi Raney <kristiraney@ventaviaresearch.com>
Subject: Daily Status Calls Updates and Action Items

Olivia Ray
Managing Member, Executive Director

<image033.png>

Ventavia Research Group, LLC
1307 8th Avenue Suite 202
Fort Worth, TX 76014
t: 817-348-0228
m: 214-394-0772
e: oliviaray@ventaviaresearch.com

<image005.png>

www.ventaviaresearch.com

<image006.png>

<image034.png>

<Daily Status Updates 9.16.2020.docx>

Ex. 22

Brook Jackson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Wednesday, September 9, 2020 1:31 PM
To: Brook Jackson
Subject: FW: Current Actions Items/Needing help

FYI

Regards,
Marnie

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 3:25 PM
To: Jailyn Reyes <jailynreyes@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Re: Current Actions Items/Needing help

Jailyn,

Thanks for making sure you reach out for help when you feel like you aren't able to get to everything.

Have you had a chance to review this with Jen yet? If not, I'd like for you to review this with her and then the two of you come up with a gameplan. If you have arleady reviewed this with Jen, then I'd like for Jen to reach out to Marnie and let her know what has been put into place to help you...and where the site still needs to help you (and pull in the leadership team).

Again, thank you for letting us know you need help!! We are here for you and we will get you to a place where you feel like you can tackle your day.

Thanks, Jailyn!

Kristi Raney
Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202

Fort Worth, TX 76104

817-348-0228 Office

817-394-1901 eFax

214-208-0390 Cell

https://www.ventaviaresearch.com/ http://www.platinum-research.net/

From: Jailyn Reyes <jailynreyes@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 3:14 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Current Actions Items/Needing help

Hello all,

I have been trying to work on all my action items by myself since we are all extremely busy, however it has been very difficult to get all my actions items completed in a timely manner. I am needing help to take some items off my plate if possible. Below, I am providing some of my action items.

With just the unblinded C4591001 and maternal C3671008, that takes all my time here at the office putting me behind on my other studies.

Unblinded C4591001- Vaccinations, Daily preparation sheets, drug confirmation sheets, and accountability logs to upload and file into Complion along with bi-weekly remote monitoring follow up visits. This takes most of the day while Nadia is doing most of the vaccines. Most of the time I do have to step in and help her with randomizing and vaccinating. I currently have over 120 documents that need to be filed but only the unblinded can do that.

C3671008-I currently have a patient in labor at 36 weeks and 5 days, working on AESI. Screening and follow up visits for the rest of the week, action items from remote monitoring visit conducted last week. I also have eDiaries to check and Bi-weekly phone calls.

AL29A- Close out visit action items that I have not been able to complete. The close out visit was conducted on 21AUG2020.

Estetra/Hot-Flash-patient coming in on 9/14/2020.

B1971057-Actions items including EDC queries.

Regards,

Jailyn Reyes
Clinical Research Coordinator & Certified
Medical Assistant

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Phone Number: (817) 348-0228
Fax Number: (817) 394-1901
Email: jailynreyes@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

Ex. 23

Rebecca Gibson

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 8:21 PM
To: Jen Vasilio; Olivia Ray; Kristi Raney; Jailyn Reyes; Marnie Fisher; Brook Jackson
Subject: RE: Current Action Items/Needing help

Great updates, Jen.

As a reminder, you do have two more coordinators joining your team in the next two weeks so hopefully, both staff can be added to all current studies and help lighten everyone's job!

We know you all are very busy right now. I appreciate you, Jailyn reaching out and waving your white flag and you, Jennifer jumping in to help her out!

I'm seeing the FW team coming together and I'm so excited for you all!

Regards,

Mercedes

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group
1307 8th Avenue, Suite 202
Ft. Worth, Tx 76104
Office: 817-348-0228
Cell: 817-845-3824
Fax Number: 817-394-1901
Email: mercedeslivingston@ventaviaresearch.com

VRG VENTAVIA RESEARCH GROUP
PLATINUM RESEARCH NETWORK

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

SILVER
CLINICAL RESEARCH CO-ORDINATOR

From: Jen Vasilio <jvasilio@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 5:18 PM

To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Jailyn Reyes <jailynreyes@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Subject: Re: Current Action Items/Needing help

Hi Ladies-

I apologize for the delay in closing the email loop on Jailyn's email, but please be assured that I have been in constant communication with Jailyn and working through all of the pending items she has listed below, since 09SEP2020 through today.

Below I have listed some of the items that are now implemented, to help lighten Jailyn's load.

Nadia is now doing all the vaccines for the COVID trial, to eliminate this from Jailyn's plate, occasionally if Nadia is behind or not in office, then Jailyn will jump in to vaccinate.

We are now utilizing the back-up CRC for the maternal trials, Linda.
Linda has been completing some of the maternal visits, when Jailyn has a monitor visit, or there are multiple maternal visits, etc.

Linda has also been helping with EDC queries, I have asked Jailyn and Linda to work to together to keep these up to date.
Linda has also offered to share "oncall" responsibilities for maternal trials with Jailyn.

Erin, is also a backup for the maternal trials and is completing training with Jailyn on Lab processing, and other trial procedures.
Erin has also offered to share "oncall" responsibilities for maternal trials with Jailyn.

Now that Nadia has moved to the fulltime research assistant position, this has also been a great help.
Nadia is also listed on the DOA and can help with Trial manager and EDC for the maternal trials.

Thank you, for bringing this to my attention.

Jen Vasilio

Site Operations Manager

Ventavia Research Group
1307 8th Ave., #202
Fort Worth, TX 76104
Cell: (817)879-5893

Office: (817)348-0228
jvasilio@ventaviaresearch.com

VRG VENTAVIA RESEARCH GROUP

PLATINUM RESEARCH NETWORK

JSN0462

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Jailyn Reyes <jailynreyes@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 3:14 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Current Actions Items/Needing help

Hello all,

I have been trying to work on all my action items by myself since we are all extremely busy, however it has been very difficult to get all my actions items completed in a timely manner. I am needing help to take some items off my plate if possible. Below, I am providing some of my action items.

With just the unblinded C4591001 and maternal C3671008, that takes all my time here at the office putting me behind on my other studies.

Unblinded C4591001- Vaccinations, Daily preparation sheets, drug confirmation sheets, and accountability logs to upload and file into Complion along with bi-weekly remote monitoring follow up visits. This takes most of the day while Nadia is doing most of the vaccines. Most of the time I do have to step in and help her with randomizing and vaccinating. I currently have over 120 documents that need to be filed but only the unblinded can do that.

C3671008-I currently have a patient in labor at 36 weeks and 5 days, working on AESI. Screening and follow up visits for the rest of the week, action items from remote monitoring visit conducted last week. I also have eDiaries to check and Bi-weekly phone calls.

AL29A- Close out visit action items that I have not been able to complete. The close out visit was conducted on 21AUG2020.

Estetra/Hot-Flash-patient coming in on 9/14/2020.

B1971057-Actions items including EDC queries.

Regards,

Jailyn Reyes
Clinical Research Coordinator & Certified
Medical Assistant

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Phone Number: (817) 348-0228
Fax Number: (817) 394-1901
Email: jailynreyes@ventaviaresearch.com

VRG VENTAVIA RESEARCH GROUP PLATINUM RESEARCH NETWORK

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

Ex. 24

- ICF errors- Training- William
  - Signatures from one page to the next not matching up
  - Brook- incorrect dates used by the patients
  - Printer copies not being clear (sloppy, cutting off footers, etc)
  - Inconsistency in where the ICF documentation process form is kept
    - Screening should be embedded in the screening source
    - Re-consent ICF documentation will be kept on top of the revised ICF
  - Update ICF documentation form with a comment section to document any questions that the patients have for the ICF process- this is a place where they can document questions and answers that the subject had during the visit – Mer will take this
    - Update ICF documentation page to have blanks for the CRC initials instead of checkboxes
    - Add a statement asking if the ICF was checked for Quality Assurance (signature verification, date formats, consistent initials, etc) by the consenter
    - CRC don't know to be documenting questions/comments/conversations had about the ICF in the progress notes
  - Proper ICF QCing process
      - CAPA needed at all three sites for the top three ICF errors- **RD** to create the CAPA for consent for all three sites and submit to Mercedes for review by **COB 9/23/2020**
- Randomization confirmations staying in the charts
  - Randomization confirmations needs to come out of the charts
  - Drug assignments need to come out (if they were in there)
    - CAPA needed that the source stated to file the IMPALA randomization and drug assignment confirmation page was required to be filed in the chart. Drug assignments were never filed in the charts however the randomization documents were but upon guidance from the sponsor, they were removed. William due to team by **COB 9/23/2020**
    - CAPA also addressing overall source issues and good documentation-William due to team by **COB 9/23/2020**
- Write overs- Training William
  - Correctly making changes
  - Patients making changes correctly on Consents-
- Source version- Training- William
  - Using the wrong version of source
    - Source control is an opportunity for growth at all sites
    - PM creates source and sends to leads for reviews
    - Sends to Regulatory to finalize and be the "keeper" of all the versions
    - Regulatory will update the headers/footers with site information for each participating site
    - Regulatory will send the approved final copy of source/revised source to sites through Complion with explanation of update and request signatures for training

        - Regulatory sends approved/revised source to sites, they will also call sites to notify revised source is being sent
        - Sites will print source from Complion vs SharePoint
        - Regulatory will need to upload source version to SharePoint
- Risk factors being checked but not going into medical history- Training – William
    - Consistency sake, primary endpoints, all these need to be compared
    - Ensure those that need to go in MedHx are listed there
    - CAPA will fall under good documentation practices
- IUD in WOCBP page but not in CM- Training- William
    - Should insertion also be placed in MedHx- preventative vs. procedure
    - Tubal ligation- documenting bilateral, etc
- Not being placed in IMPALA until later in the visit (instead of after consent) – William training
    - Waiting on response from Arturo on this
- Blanks in the charts (unscheduled visit with physical page not completed)- William Training
- Patients location during 30 minute waiting period- Training Mer
    - Be in the waiting area where the receptionist can see the patients
    - If in the hallway, a staff member needs to be in the hallway with a work station
    - Patients need to be brought back into a room for 30-minute post observation period
- CM indication not matching med hx term- Training William
    - Back muscle spasms and degenerative disk disease listed in MedHX
    - CM listed as taken for back pain but no back pain in MedHx
    - Procedures listed in MedHx but not indication for procedure
    - MedHx start dates and CM start dates not lining up (CM starting before MedHx condition)
- Medical History page- revised to take out question asking if the subject has past or present medical or surgical history. - Kate
    - Add yes/no after the bolded question
    - Taking out Yes/No for each system
- Progress noting issues- Training William
    - Pt used MLR (pt info sheet) vs MHR (DL) no progress note as to why CRC used license vs what pt put on MedHX list
    - Devices- Trianing
    - Pt initially requested a device and one was given
    - At next visit, requested to use the app and we didn't document if the device was collected from the subject
- Schedule of events- Training Mer
    - Remove from charts all together
    - PMs created laminated "kit" with rings for all the pages that are needed for patient education.
    - One will go back with patients at each visit
    - This can be reviewed during the pre-study training
    - Create NTF that statement in the source "Has the protocol Schedule of Activities been reviewed to ensure all visit procedures have been completed" is signed off by the CRC and is being reviewed on a master copy – MER

- E-diary email about AEs- what is the question here? - Training William
  - Symptoms noted in the e-diary regardless of if they are ongoing after Day 7 or not are not to be reported as AEs
  - Patients outside of the reactogenicity subset if they have symptoms after vaccine should be reporting in the illness visit e-diary page
  - Protocol pages 92-95
- E-diary- Training William
  - Visit 2 and Visit 3- question regarding e-diary issues
  - Source to be updated asking if there are problems with the e-diary
    - Separate question if the subject missed any days during the e-diary reporting period
  - E-diaries are to be printed on Day 8 (after 7 day period) and signed by the PI as soon as possible (within 2-3 days from printing)
  - Patient ID/initials and Study number aren't on the e-diary print-out-
- Source document of WOCBP- Training MER- Video
  - Signature statement should only be signed if the subject's methods of contraception could change while in the study
  - WOCBP should be updated with an NA box for signature if post-menopausal/hysterectomy
  - NTF- clarifying what the statement is meant to say and what the CRC and Investigator are signing on - MER
  - Source to be updated clarifying statement in WOCBP template and study source. MER

Resolution- create a check list for what needs to be completed in each chart and export a list of patients for items to be completed/taken out of each chart.

Get all charts completed by **COB on Friday**

Ex. 25

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281066	V3	24Sep2020 922	32	955	24Sep2020 1011	24 Sep 2020 1016	24Sep2020 ME
11281036	V3	24Sep2020 1013	41	1054	24Sep2020 1117	24Sep2020 1125	24Sep2020 ME
1128 1064	V3	24Sep2020 1055	40	1135	24Sep2020 1244	24Sep2020 1216	24Sep2020 ME
11281072	V3	24Sep2020 1145	31	1216	24Sep2020 1241	24Sep2020 1545 ME	24Sep2020 ME
1128 1070	V3	24Sep2020 1430	35	1505	24Sep2020 1524	24Sep2020 1536	24Sep2020 ME
1128 1067	V3	24Sep2020 1454	31	1525	24Sep2020 1542	24Sep2020 1546 ~~1611~~ ME 24Sep2020	24Sep2020 ME
1128 1057	V3	24Sep2020 1511	31	1542	24Sep2020 1606	24Sep2020 1611 ~~1639~~ ME	24Sep2020 ME
1128 1015	V3	24Sep2020 1535	35	1610	24Sep2020 1628	24Sep2020 1639	24Sep2020 ME
1128 1013	V3	24Sep2020 11:01	309	1610	24Sep2020 1629	24Sep2020 1642	24Sep2020 ME

JSN0468

120

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze Immediately)	CRC Initials/Date
11281042	V3	23sept 2020 1101	34	1133	23Sep2020 1151	23Sep2020 1156	23Sep2020 me
11281035	V3	23sep2020 1112	62	1150	23Sep2020 1206	23Sep2020 1208	23Sep2020 me
11281308	V1	23Sep2020 1243	56	1314	23Sep2020 1333	23Sep2020 1337	23Sep2020 me
1128~~1306~~ 1036 me 23 Sep 2020	V3	23Sep2020 1255	69	1314	23Sep2020 1410	23Sep2020 1416	23Sep2020 me
11281054	V3	23Sep2020 1416	39	1455	23Sep2020 1510	23Sep2020 1521	23Sep2020 me
11281384	V1	23Sep2020 me 1427	39	~~1518~~ 1528 23 me Sep2020	23Sep2020 1530	23Sep2020 1533	23Sep2020 me
11281039	V3	23Sep2020 me ~~1534~~ 1543	58	1616	23Sep2020 1632	23Sep2020 1637	23Sep2020 me
11281030	V3	24Sep2020 0846	66	0920	24Sep2020 936	24Sep2020 944	24Sep2020 me
11281046	V3	24 Sep 2020 856	76	0920	24Sep2020 952	24 Sep 2020 957	24Sep2020 me

JSN0469

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes)	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1022	V3	21 Sep 2020 1013	32	1045	21sep2020 1702	21 Sep 2020 1710	21Sep2020 me
1128 1008	V3	22 Sep 2020 944	60	1016	22Sep2020 1033	22Sep2020 1039	22 Sep 2020 me
1128 1007	V3	22 Sep 2020 941	57	1016	22Sep2020 1038	22Sep2020 1042	22 Sep 2020 me
1128 1026	V3	22 Sep 2020 1014	58	1044	22Sep2020 1102	22Sep2020 1109	22Sep2020 me
1128 1031	V3	22Sep 2020 1212	32	1244	22Sep2020 1311	22Sep2020 1320	22Sep 2020 me
1128 1047	V3	22Sep2020 1408	48	1440	1489 22Sep2020	22Sep2020 1503	22Sep2020 me
1128 1024	V3	22Sep 2020 1530	38	1608	22Sep2020 1626	22Sep2020 1634	22Sep2020 me
1128 1032	V3	23Sep2020 900	33	933	23Sep2020 950	23Sep 2020 955	23 Sep 2020 me
1128 1033	V3	23Sep2020 932	41	1009	1025 23Sep2020	23 Sep 2020 1030	23Sep2020 me

JSN0470

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze Immediately)	CRC Initials/Date
1128/1016	V3	18 sept 2020 1612	30	1642	18 Sept 2020 1712	18 Sept 2020 1717	18 Sept 2020 me
1128/1318	V1	18 Sept 2020 1619	38	1653	18 Sept 2020 1712	18 Sept 2020 1717	18 Sept 2020 me
1128/1029	V3	18 sept 2020 1650	32	~~1654~~ 1720 18 Sept 2020 me	18 Sept 2020 1738	18 Sept 2020 1740	18 Sept 2020 me
1128/1043	V3	21 sept 2020 1010	42	1052	~~1~~ 1122 21 Sep 2020 me	21 Sep 2020 1134	21 Sep 2020 me
1128/1041	V3	21 sept 2020 1010	42	1052	21 Sep 2020 1122	21 Sept 2020 1134	21 sep 2020 me
1128/1040	V3	21 Sep 2020 1015	45	1100	21 sept 2020 1144	21 sept 2020 1151	21 Sep 2020 me
1128/1037	V3	21 sep 2020 1215	60 didn't clot	1434	21 sep 2020 1440	21 sep 2020 1444	21 sep 2020 me
~~1128/10~~ ERROR me 21 Sep 2020							me
~~1128/~~ ERROR 21 Sep 2020							me

JSN0471

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1006	V3	18 sept 2020 1045	30	1115	18 sept 2020 1123	18 sept 2020 1130	18 sept 2020 ma
1128 1379 ✓	V1	18 sept 2020 1059	62	~~1110~~ 1125 ma 18 sept 2020	18 sept 2020 1133	18 sept 2020 1140	18 sept 2020 ma
1128 1025	V3	18 sept 2020 1059	62	1125	18 sept 2020 1134	18 sept 2020 1143	18 sept 2020 ma
1128 1004	V3	18 sept 2020 9:09	49	940	18 sept 2020 948	18 sept 2020 1023	18 sept 2020 ma
1128 1002	V3	18 sept 2020 1240	30	13:11	18 sept 2020 13:34	18 sept 2020 13:36	18 sept 2020 ma
1128 1382	V1	18 sept 2020 1335	38	1359	18 sept 2020 1426	18 sept 2020 1429	18 sept 2020 ma
1128 1383	V1	18 sept 2020 1347	36	1417	18 sept 2020 1442	18 sept 2020 1444	18 sept 2020 ma
~~1128 1227~~ 11281020 ma 18 sept 2020	V3	18 Sept 2020 1422	42	1504	18 Sept 2020 1522	18 Sept 2020 1523	18 Sept 2020 ma
1128 ~~1201~~ 1021 ma 18 sept 2020	V3	18 Sept 2020 1538	38	1600	18 Sept 2020	18 Sept 2020	18 Sept 2020 ma

JSN0472

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes)	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281262	V1	17SEP2020 0957	32	~~17SEP2020~~ ~~1024~~ 1029	17SEP2020 1043	17SEP2020 1050	AB 17SEP2020
11281027	V3	17SEP2020 1007	34	1041	17SEP2020 1058	17SEP2020 1103	AB 17SEP2020
11281376	V1	17SEP2020 1010	31	1041	17SEP2020 1059	17SEP2020 1103	AB 17SEP2020
11281018	V3	17SEP2020 1043	41	1125	17SEP2020 11:45	17SEP2020 11:50	17 Sep 2020 [initials]
11281377	V1	17SEP2020 1137	68	1245	17SEP2020 1304	17SEP2020 1307	17SEP2020 ABR
11281378	V1	17SEP2020 1157	48	1245	17SEP2020 1305	17SEP2020 1307	17SEP2020 ABR
11281380	V1	17SEP2020 1425	30	1455	17SEP2020 1323	17SEP2020 1325	17SEP2020 ABR
11281381	V1	17SEP2020 1453	32	1525	17SEP2020 1544	17SEP2020 1549	ABR 17SEP2020
11281017	V3	18 Sept 2020 1030	32	1102	18 Sept 2020 1130	18 Sept 2020 1134	18 Sept 2020 me

JSN0473

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281001	V3	16 SEP 2020 1145	80	1305 ~~1401~~ ABR 9-16-2020	16 SEP 2020 1330	16 SEP 2020 1354	ABR 16SEP2020
11281371	V1	16 SEP 2020 1205	60	1305 ~~1401~~ ABR 9-16-2020	16 SEP 2020 1330	16 SEP 2020 1354	ABR 16SEP2020
11281370	V1	16SEP2020 1324	37	1401	16SEP2020 1435	16SEP2020 1441	ABR 16SEP2020
11281009	V3	16 SEP 2020 1325	36	1401	16SEP2020 1438	16SEP2020 1441	ABR 16SEP2020
11281372	V1	16SEP2020 1323	38	1401	16SEP2020 1438	16SEP2020 1441	ABR 16SEP2020
11281373	V1	16SEP2020 1431	31	1502	16SEP2020 1534	16SEP2020 1535	ABR 16SEP2020
11281374	V1	16SEP (?) 2020 1624	32	1656	16SEP2020 1713	16SEP2020 1715	AB 16SEP2020
11281375	V1	16 SEP 2020 1645	31	1716	16SEP2020 1750	16 SEP 2020 1758	AB 16SEP2020
11281011	V3	17 SEP 2020 0854		—	17SEP2020 1015 AB	17 SEP2020 1022 AB	AB 16SEP2020

JSN0474

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze Immediately)	CRC Initials/Date
n/a							
1128 1343	V1	15sept2020 1403	30	15 sept2020 1453	15sept2020 1500	15sept2020 1512	15sept2020 mg
1128 1302	V1	1212	40	15sept2020 1300	15 sept 2020 1322	15sept2020 1345	15sept2020 mg
1128 1304	V1	1426	42	15sept2020 1458	15sept2020 1509	15sept2020 1530	15sept2020 mg
1128 1305	V1	1428	40	15sept2020 1458	15sept2020 1512	15sept2020 1538	15sept2020 mg
1128 1366	V1	1632	63	1735	1740	17:43	JS 09/15/2020
1128 1368	V1	955	35	16sept2020 1030	16 Sept 2020 1042	16 Sept 2020 1046	16 sept 2020 mg
1128 1307	V1	1007	30	16 sept 2020 1033	16 Sept 2020 1050	16 Sept 2020 1053	16 Sept 2020 mg
1128 1010	V3	1108		—	16SEP2020 1300 TB	16SEP2020 1340 TB	16SEP2020 TB

JSN0475

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1353	V1	14sept2020 1200	30	1244	14sept2020 1300	14sept2020 1304	14sept2020 me
1128 1005	V3	14sept2020 1442	38	1549	14sept2020 1556	14sept2020 1600	14sept2020 me
1128 1354	V1	14sept2020 1518	31	1549	14sept2020 1620	14sept2020 1622	14sept2020 me
1128 1355	V1	14sept2020 1519	32	1550	14sept2020 1620	14sept2020 1622	14sept2020 me
1128 1356	V1	14sept2020 1605	30	1640	14sept2020 1645	14sept2020 1648	14sept2020 me
1128 1358	V1	15sept2020 923	45	1012	15sept2020 1028	15sept2020 1030	15sept2020 me
1128 1357	V1	15sept2020 924	45	1012	15sept2020 1028	15sept2020 1031	15sept2020 me
1128 1359	V1	15sept2020 1014	30	1050	15sept2020 1058	15sept2020 1100	15sept2020 me
1128 1360	V1	15sept2020 1031	35	1103	15sept2020 1127	15sept2020 1129	15sept2020 me

JSN0476

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze Immediately)	CRC Initials/Date
11281344	V1	12sept2020 1126	36	1200	12sept2020 1216	12sept2020 1220	12sept2020 ma
11281347	V1	12Sept2020 1125	35	1159	12Sept2020 1216	12Sept2020 1218	12sept2020 ma
11281346	V1	12sept2020 1203	43	1240	12sept2020 1252	12sept2020 1254	12sept2020 ma
11281348	V1	12sept2020 1344	30	1416	12sept2020 1443	12sept2020 1503	12sept2020 ma
11281350	V1	12sept2020 1403	38	1441	12sept2020 1501	12sept2020 1508	12sept2020 ma
11281349	V1	12sept2020 1336	30	1408	12sept2020 1443	12sept2020 1503	12sept2020 ma
11281351	V1	12sept2020 1441	62	1548	12sept2020 1601	12sept2020 1616	12sept2020 ma
11281352	V1	12sept2020 1547	36	1634			
					↑ done 14 sept 2020 By April		

JSN0477

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128/1331	V1	11Sept2020 1144	38	1436	11Sept2020 1440	11Sept2020 1450	11Sept2020 MZ
1128/1333	V1	11Sept2020 1302	38	1436	11Sept2020 1442	11Sept2020 1453	11Sept2020 MZ
1128/1336	V1	11Sept2020 1400	30	1430	11Sept2020 1500	11Sept2020 1502	11Sept2020 MZ
1128/1335	V1	11Sept2020 1414	39	1453	11Sept2020 1502	11Sept2020 1530	11Sept2020 MZ
1128/1339	V1	11Sept2020 1532	32	1602	11Sept2020 1625	11Sept2020 1630	11Sept2020 MZ
1128/1341	V1	11Sept2020 1602	31	1635	11Sept2020 1700	11Sept2020 1705	11Sept2020 MZ
11281342	V1	11Sept2020/17:25	45	18:10	11Sept2020 1828	11Sept2020 1829	11Sept2020 MZ
1128/1345	V1	11Sept2020 959	30	1032	12Sept2020 1055	12Sept2020 1056	12Sept2020 MZ
1128/1343	V1	11Sept2020 1003	30	1034	12Sept2020 1054	12Sept2020 1056	12Sept2020 MZ

JSN0478

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128/324	V1	10Sept2020 ma 1505	~~35~~ ~~30~~ ME 10 sept2020	1540	10Sept2020 1542	10Sept2020 1548	10Sept2020 me Red Serum
1128/323	V1	10Sept2020 ma 1540	30	1614	10Sept2020 1645	10Sept2020 1650	10 Sept2020 me
1128/326	V1	10 Sept 2020 ma 1621	30	1703	10Sept2020 1715	10 Sept2020 1726	10Sept2020 me
1128/327	V1	10 Sept 2020 1705	30	1738	10Sept2020 1739	10Sept2020 1742	10Sept2020 me
1128/328	V1	LBL 9-10-2020 17~~1458~~	32	18~~30~~ LBL 9-10-20	10SEP2020 1848	10SEP2020 1850	LBL 10SEP2020
1128/329	V1	10SEP2020 1901	36	1937	10SEP2020 2003	10SEP2020 2006	TB 10SEP2020
1128/317	V1	11Sept2020 9:19	32	10:08	11Sept2020 1025	11Sept2020 1027	11Sept2020 me
1128/330	V1	11Sept2020 1119	36	1155	11Sept2020 1205	11Sept2020 1210	11Sept2020 me
1128/332	V1	11Sept2020 1122	36	1155	11Sept2020 1209	11Sept2020 1215	11Sept2020 me

JSN0479

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1312	V1	1301	30	1400	9Sept2020 1405	9Sept2020 1408	9Sept2020 me
1128 1313	V1	1514	30	1540	9Sept2020 1543	9Sept2020 1549	9Sept2020 me
1128 1315	V1	1544	30	1615	9 Sept 2020 1622	9Sept2020 1640	9Sept2020 me
1128 1314	V1	1558	30	1615	9Sept2020 1642	9Sept2020 1656	9Sept2020 me
1128 1316	V1	1601	30	1648	9Sept2020 1651	9 Sept2020 1700	9Sept2020 me
18 Sept 2020 me 1128 1317 9	V1	1740	30	1820	9Sept2020 1806	09 Sept2020 1834	9Sept2020 me
1128 1320	V1	11:09	30	1147	10 Sept 2020 1215	10 Sept2020 1230	10 Sept2020 me
1128 1321	V1	1315	30	1147	10 Sept2020 1447	10 Sept2020 1450	10 Sept2020 me
1128 1322	V1	1353	30	1447	10 Sept 2020 1449	10 Sept2020 1449	10 Sept2020 me

JSN0480

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1302	V1	1548	30	1615	8sept2020 1845	8sept2020 1900	8 sept2020 ma
1128 1299	V1	1504	30	1620	8sept2020 1845	8sept2020 1900	8sept2020 ma
1128 1305	V1	1548	30	1850	8sept2020 1858	8sept2020 1900	8 sept2020 ma
1128 1303	V1	1649	30	1840	8sept2020 1900	8sept2020 1920	8sept2020 ma
1128 1304	V1	1058	30	1845	8sept2020 1900	8sept2020 1920	8sept2020 ma
1128 1307	V1	9sept2020 1045	30	1207	9sept2020 1228	9sept2020 1229	9sept2020 ma
1128 1306	V1	9sept2020 1040	30	1207	9sept2020 1228	9sept2020 1229	9sept2020 ma
1128 1309	V1	9sept2020 1209	30	1245	9sept2020 1349	9sept2020 1340	9sept2020 ma
1128 1311	V1	9sept2020 1243	30	1340	9sept2020 1342	9sept2020 1355	9sept2020 ma

JSN0481

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1292	V1	04 Sep 2020 17:16	30 min	17:46	04/Sep/2020 18:19	04/Sep/2020 18:20	[initials] 09/04/2020
1128 1293	V1	08 Sept 2020 1036	30	11:08	08/Sept/2020 1132	08 Sept 2020 1135	ma 8Sept2020
1128 1294	V1	08 Sept 2020 1035	50	11:15	08/Sept 2020 1134	08 Sept 2020 1135	ma 8Sept 2020
1128 1295	V1	08 Sept 2020 1049	30	11:40	08 Sept 2020 11:52 ~~1152~~ me 8/Sept/2020	08 Sept 2020 1155 ~~[illegible]~~ ma 8/Sept/2020	ma 8/Sept/2020
1128 1296	V1	08 Sept 2020 1132	30	1200	8 Sept 2020 1205	8 Sept 2020 1207	8 Sept 2020 ma
1128 1297	V1	08 Sept 2020 1226	30	1303	8 Sept 2020 1305	8 Sept 2020 1310	8 Sept 2020 ma
1128 1298	V1	08 Sept 2020	30	1610	8 Sept 2020 1620	8 Sept 2020 1622	8 Sept 2020 ma
1128 1300	V1	08 Sept 2020 1505	30	1630	8 Sept 2020 1638	8 Sept 2020 1640	8 Sept 2020 ma
1128 1301	V1	08 Sept 2020 1451	30	16:00	8 Sept 2020 1620	8 Sept 2020 1622	8 Sept 2020 ma

JSN0482

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 | **PI: Mark Koch, MD** | **Site: 1128**
Laboratory: Covance | **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1281	V1	03Sept2020 1055	30	03Sept2020 1713	03Sept2020 1732	03 Sept 2020 1740	03Sept2020 MA
1128 1283	V1	03 Sept 2020 1645	30	03Sept2020 1712	03Sept2020 1735	03 Sept 2020 1740	03Sept2020 MA
1128 1282	V1	03Sept 2020 1750	30	03Sept2020 1824	03Sept2020 1840	03 Sept 2020 1900	03Sept2020 MA
1128 1284	V1	04Sept2020 1115	30	04Sept2020 1140	04Sept2020 1240	04Sept2020 1309	04Sept2020 MA
1128 1285	V1	04Sept2020 1150	30	04Sept2020 1202	04Sept2020 1255	04Sept2020 1302	04Sept2020 MA
1128 1286	V1	04Sept2020 1252	30	04Sept2020 1202	04Sept2020 1240	04Sept2020 1309	04Sept2020 MA
1128 1288	V1	04Sept2020 1223	30	04Sept2020 1302	04Sept2020 1310	04Sept2020 1310	04Sept2020 MA
1128 1289	V1	04Sept2020 1248	~~20~~ 30 MA 04Sept2020	04Sept2020 1327	04Sept 2020 1357	04 Sept 2020 1359	04Sept2020 MA
1128 1291	V1	04Sept2020 14:40	30	04Sept2020 1515	04Sept2020 1530	04Sept2020 1531	04 Sept 2020 MA

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	**Visit Date**	**Draw Date/Time** Thoroughly mix the blood by inverting the tube five times	**Total Clot Time in minutes**	**Time in Centrifuge** (samples should be spun at **1500-2000 x g for at least 15 minutes**	**Aliquoting Date/Time**	**Date/Time in -20°C freezer for Plasma samples** (Freeze immediately)	**CRC Initials/Date**
1128/271	V1	02sept 2020 1416	30	03sept 2020 1530	03Sept 2020 1536	03 sept 2020 1550	MR 03sept 2020
1128/273	V1	02Sept2020 1558	30	1620	1624	03Sept 2020 1630	MR 03Sept2020
1128/274	V1	03Sept2020 1147	30	03 Sept 2020 1257	03 Sept2020 1300	03 Sept 2020 1302	MR 03 Sept 2020
1128/275	V1	03Sept2020 1207	30	03 Sept 2020 1257	03 Sept 2020 1303	03 Sept 2020 1302	03Sept2020 MR
1128/276	V1	03sept2020 1308	30	03sept2020 1340	03 sept 2020 1340	03Sept 2020 1432	03 sept 2020 MR
1128/278	V1	03sept2020 1440	30	03sept2020 1520	03 Sept2020 1530	03 Sept 2020 1549	03 Sept2020 MR
1128/277	V1	03sept 2020 1524	30	03 sept 2020 1537	03sept2020 1625	03Sept2020 1625	03Sept2020 MR
1128/279	V1	03 sept 2020 1543	30	03sept2020 1624	03 Sept 2020 1640	03sept2020 1650	03Sept 2020 MR
1128/280		03sept2020 1636	30	03Sept 2020 1700	03sept2020 1709	03 sept 2020 1730	03 sept 2020 MR

JSN0484

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128/261	V1	01 Sept 2020 1919	01 Sept 2020 1921	30	01 Sept 2020 1950	01 Sept 2020 1956	01 Sept 2020 ma
1128/260	V1	01 Sept 2020 1900	01 Sept 2020 1920	30	01 Sept 2020 1950	01 Sept 2020 1956	01 Sept 2020 ma
1128/246	V1	02 Sept 2020 0855	30	02 Sept 2020 0930	02 Sept 2020 0949	01 Sept 2020 1000	02 Sept 2020 ma
1128/263	V1	02 Sept 2020	30	02 Sept 2020	02 Sept 2020	02 Sept 2020	02 Sept 2020 ma
1128/264	V1	02 Sept 2020 1043	30	02 Sept 2020 1122	02 Sept 2020 1146	02 Sept 2020 1148	02 Sept 2020 ma
1128/265	V1	02 Sept 2020 1050	30	02 Sept 2020 1146	02 Sept 2020 1200	02 Sept 2020 1202	02 Sept 2020 ma
1128/267 Arriv	V1	02 Sept 2020	30	02 Sept 2020	02 Sept 2020 1208	02 Sept 2020 1210	02 Sept 2020 ma
1128/269	V1	02 Sept 2020 1338	30	ma 1428 02 Sept 2020 ~~1350~~	02 Sept 2020 1440	02 Sept 2020 1456	02 Sept 2020 ma
1128/268	V1	02 Sept 2020	~~30~~ 30 ma 01 Sept 2020	1350	02 Sept 2020 1352	02 Sept 2020 1352	02 Sept 2020 ma

send 2mL 2mL 5mL ma 02 Sept 2020

JSN0485

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 **PI: Mark Koch, MD** **Site: 1128**
Laboratory: Covance **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281248	V1	01 sept 2020 1223	41	01 Sept 2020 1318	01 Sept 2020 1326	01 Sept 2020 1328	01 Sept 2020 MR
11281249	V1	01 sept 2020 1249	36	01 Sept 2020 1330	01 Sept 2020 1335	01 Sept 2020 1340	01 Sept 2020 MR
11281250	V1	01 Sept 2020 1301	32	01 Sept 2020 1337	01 Sept 2020 1355	01 Sept 2020 1400	01 Sept 2020 MR
11281251	V1	01 sept 2020 1430	30	01 sept 2020 1501	01 Sept 2020 15:09	01 Sept 2020 15:16	01 Sept 2020 MR
1128 1252	V1	01 sept 2020 1346	30	01 sept 2020 1430	01 Sept 2020 1519	01 Sept 2020 1527	01 Sept 2020 MR
1128 1253	V1	01 Sept 2020 1529	30	01 sept 2020 1605	01 Sept 2020 1628	01 Sept 2020 1720	01 Sept 2020 MR
1128 1256	V1	01 sept 2020 1659	30	01 sept 2020 1715	01 sept 2020 1728	01 Sept 2020 1805	01 Sept 2020 MR
1128 1257	V1	01 sept 2020	30	01 Sept 2020 1730	01 Sept 2020 1750	01 Sept 2020 1810	01 Sept 2020 MR
1128 1255	V1	01 Sept 2020 1719	30	01 Sept 2020 1746	01 Sept 2020 1748	01 Sept 2020 1753	01 Sept 2020 MR

JSN0486

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1237	V1	31 Aug 2020 1508	39	31 Aug 2020 1541	31 Aug 2020 1605	31 Aug 2020 16:10	ma 31 Aug 2020
1128 1239	V1	31 Aug 2020 1510	35	31 Aug 2020 1545	31 Aug 2020 1615	31 Aug 2020 1630	ma 31 Aug 2020
1128 1240	V1	31 Aug 2020 1014	30	31 Aug 2020 1637	31 Aug 2020 1053	31 Aug 2020 1700	ma 31 Aug 2020
1128 1241	V1	31 Aug 2020 1558	30	31 Aug 2020 1637	31 Aug 2020 1655	31 Aug 2020 1705	31 Aug 2020 ma
1128 1242	V1	31 Aug 2020 1629	46	31 Aug 2020 1717	31 Aug 2020 1742	31 Aug 2020 1758	31 Aug 2020 ma
1128 1243	V1	31 Aug 2020 1714	30	31 Aug 2020 1815	31 Aug 2020 1824	31 Aug 2020 1829	31 Aug 2020 ma
1128 1244	V1	01 Sept 2020 0940	30	01 Sept 2020 1030	01 Sept 2020 1039	01 Sept 2020 1040	01 Sept 2020 ma
1128 1245	V1	01 Sept 2020 1021	~~30~~ 01 Sept 2020 ma 01	01 Sept 2020 1146	01 Sept 2020 1150	01 Sept 2020 1152	01 Sept 2020 ma
1128 1247	V1	01 Sept 2020	30	01 Sept 2020	01 Sept 2020 1145	01 Sept 2020 1150	01 Sept 2020 ma

JSN0487

Page ~~28~~ 27 of __
ma 09/05/2020

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1230	V1	31 Aug 2020 1035	35	31 Aug 2020 11:10	31 Aug 2020 1158	31 Aug 2020 12:11	MA 31 Aug 2020
1128 1231	V1	31 Aug 2020 1049	30	31 Aug 2020 11:10	31 Aug 2020 1159	31 Aug 2020 12:21	MA 31 Aug 2020
1128 1229	V1	31 Aug 2020 1030	~~30~~ 42 MA 31 Aug 2020	31 Aug 2020 11:12	31 Aug 2020 1200	31 Aug 2020 1222	MA 31 Aug 2020
1128 1232	V1	31 Aug 2020 1141	30	31 Aug 2020 1233	31 Aug 2020 1245	31 Aug 2020 1240	MA 31 Aug 2020
1128 1233	V1	31 Aug 2020 1232	42	31 Aug 2020 ~~110~~ 1310 (Aug 2020)	31 Aug 2020 1331	31 Aug 2020 1333	MA 31 Aug 2020
1128 1234	V1	31 Aug 2020 1315	36	1345 31 Aug 2020	1352 31 Aug 2020	1418 31 Aug 2020	MA 31 Aug 2020
1128 1236	V1	31 Aug 2020 1345	30	1405 31 Aug 2021	1430 31 Aug 2020	1438 31 Aug 2020	MA 31 Aug 2020
1128 1235	V1	31 Aug 2020 1434	30	1504 31 Aug 2020	1528 31 Aug 2020	1535 31 Aug 2020	MA 31 Aug 2020
1128 1238	V1	31 Aug 2020 1500	36	31 Aug 2020 1536	31 Aug 2020 1554	31 Aug 2020 1600	31 Aug 2020 MA

JSN0488

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281221	28 AUG 2020 V1	28AUG2020 1043	34	28 AUG2020 1117	28AUG2020 1142	28 AUG 2020 1143	LBL 28AUG2020
11281220	28 AUG 2020	28 AUG2020 1133	31	28 AUG2020 1204	28 AUG2020 1223	28 AUG 2020 1224	LBL 28AUG2020
11281222	28AUG 2020	28 AUG 2020 1204	49	28 AUG 2020 1255	28 AUG 2000 1325	28 AUG 2020 1328	LBL 28 AUG 2020
11281223	28AUG 2020	28 AUG 2020 1225	30	28AUG2020 1255	28 AUG2020 1326	28AUG2020 1328	LBL 28 AUG2020
11281224	28AUG 2020	28 AUG2020 1316	41	28AUG2020 1357	28 AUG2020 1617	28 AUG 2020 1618	LBL 28AUG2020
11281225	28AUG 2020	28 AUG 2020 1438	34	28AUG2020 1612	28 AUG2020 1634	28 AUG2020 1639	LBL 28AUG2020
11281226	28 AUG 2020	28 AUG2020 1542	30	28AUG2020 1612	28AUG2020 1636	28 AUG 2020 1639	LBL 28AUG2020
11281227	28 AUG 2020	28 AUG2020 1603	37	28 AUG2020 1640	28 AUG2020 1657	28 AUG2020 1658	LBL 28 AUG 2020
11[illegible]1228	V1	1015 31 Aug 2020	40	31 Aug 2020 1107	31 Aug 2020 1130	31 Aug 2020 1145	MA 31 Aug 2020

JSN0489

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281209	V1	1045 27 Aug 2020	30	1122 27 Aug 2020	1150 27 Aug 2020	1152 27 Aug 2020	MC 27 Aug 2020
11281212	V1	27AUG2020 1200	51	27AUG2020 1251	27AUG2020 1402	27AUG2020 1414	LBR 27AUG2020
11281213	V1	27AUG2020 1213	38	27AUG2020 1251	27AUG2020 1412	27AUG2020 1414	LBR 27AUG2020
11281214	V1	27AUG2020 1515	31	27AUG2020 1546	27AUG2020 1605	27AUG2020 1607	LBR 27AUG2020
11281216	V1	27AUG2020 1635	37	27AUG2020 1712	27AUG2020 1728	27AUG2020 1730	LBR 27AUG2020
11281215	V1	27AUG2020 1657	42	27AUG2020 1739	27AUG2020 1758	27AUG2020 1802	LBR 27AUG2020
11281218	V1	27AUG2020 1709	30	27AUG2020 1739	27AUG2020 1759	27AUG2020 1802	LBR 27AUG2020
11281217	V1	27AUG2020 1731	30	27AUG2020 1801	27AUG2020 1818	27AUG2020 1819	LBR 27AUG2020
11281219	V1	28AUG2020 1007	35	28AUG2020 1042	28AUG2020 1107	28AUG2020 1109	LBR 28AUG2020

JSN0490

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128/203	V1	1215 26Aug2020	~~27~~ 30	1245 26Aug2020	1250 26Aug2020	1300 26Aug2020	MC 26Aug2020
1128/204 26 Aug 2020 [illegible]	V1	1240 ~~1307~~ MC 26Aug2020	30	1335 26Aug2020	1348 26Aug2020	1401 26Aug2020	MC 26Aug2020
1128/204 26 Aug 2020 [illegible]	V1	1307 26Aug2020	30	1338 26Aug2020	1340 26Aug2020	1345 26Aug2020	MC 26Aug2020
1128/205	V1	1527 26Aug2020	30	1616 26Aug2020	1619 26Aug2020	1620 26Aug2020	MC 26Aug2020
1128/206	V1	1605 26Aug2020	30	1704 26Aug2020	1708 26Aug2020	1718 26Aug2020	MC 26Aug2020
1128/207	V1	1614 26Aug2020	30	1702 26Aug2020	1714 26Aug2020	1720 26Aug2020	MC 26Aug2020
✓1128/208	V1	1658 26Aug2020	30	1733 26Aug2020	1808 26Aug2020	1812 26Aug2020	AJS 26AUG2020 MC 26Aug2020
1128/211	V1	1011 27Aug2020	30	1036 27Aug2020	1122 27Aug2020	1124 27Aug2020	MC 27Aug2020
1128/210	V1	27Aug2020	30	1036 27Aug2020	1122 27Aug2020	1132 27Aug2020	MC 27Aug2020

JSN0491

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1192	V1	1637 25 Aug 2020	30	1740 25Aug2020	1750 25 Aug 2020	1808 25 Aug 2020	MG 25Aug2020
1128 1195	V1	1650 25 Aug 2020	30	1750 25 Aug 2020	1800 25 Aug 2020	1808 25 Aug 2020	MG 25Aug2020
1128 1196	V1	1753 25 Aug 2020	30	1826 25Aug2020	1825 25Aug2020	1828 25Aug2020	MG 25Aug2020
1128 1197	V1	1823 25 Aug 2020	30	1844 25Aug2020	1850 25Aug2020	1853 25Aug2020	MG 25Aug2020
1128 1194 (MG 25Aug2020)	V1	1823 25 Aug 2020	30	1904 25Aug2020	1908 25Aug2020	1922 25 Aug2020	MG 25Aug2020
1128 1198	V1	1000 26 Aug 2020	30	1035 26 Aug 2020	1056 26 Aug 2020	1057 26 Aug 2020	MG 26Aug2020
✓ 1128 1199	V1	1119 26 Aug 2020	30	1156 26 Aug 2020	1210 26 Aug 2020	1215 26 Aug 2020	MG 26Aug2020
1128 1201	V1	1133 26 Aug 2020	30	1210 26 Aug 2020	1236 26 Aug 2020	1238 26 Aug 2020	MG 26 Aug 2020
1128 1202	V1	1134 26 Aug 2020	30	1218 26 Aug 2020	1238 26 Aug 2020	1240 26 Aug 2020	MG 26 Aug 2020

JSN0492

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
1128 1184	V1 25Aug2020	1136 25Aug2020	30	1208 25Aug2020	1219 25Aug2020	1228 25Aug2020	MR 25Aug2020
1128 1186	V1	1238 25Aug2020	30	1310 25Aug2020	1335 25Aug2020	1346 MR 25Aug2020	MR 25Aug2020
1128 1185	V1	1245 25Aug2020	30	1320 25Aug2020	1335 25Aug2020	1346 MR 25Aug2020	MR 25Aug2020
1128 1187	V1	1255 25Aug2020	30	1330 25Aug2020	1344 25Aug2020	1349 25Aug2020	MR 25Aug2020
1128 1189	V1	1438 25Aug2020	30	1548 25Aug2020	1555 25Aug2020	1558 25Aug2020	MR 25Aug2020
1128 1190 25Aug2020 MR	V1	1506 25Aug2020	30	1610 25Aug2020	1628 25Aug2020	1728 25Aug2020	MR 25Aug2020
1128 1188	V1	1532 25Aug2020	30	1610 25Aug2020	1626 25Aug2020	1728 25Aug2020	MR 25Aug2020
1128 1191	V1	1608 25Aug2020	30	1658 25Aug2020	1722 25Aug2020	1728 25Aug2020	MR 25Aug2020
1128 1193	V1	1620 25Aug2020	30	1658 25Aug2020	1728 25Aug2020	1728 25Aug2020	MR 25Aug2020

JSN0493

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001
Laboratory: Covance

PI: Mark Koch, MD

Site: 1128
Sampling Type: Blood

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281174	V1	1429 24 Aug 2020	30	1447 24 Aug 2020	1519 24 Aug 2020	1520 24 Aug 2020	MR 24 Aug 2020
11281173	V1	1418 24 Aug 2020	30	1447 24 Aug 2020	1519 24 Aug 2020	1520 24 Aug 2020	MR 24 Aug 2020
11281176	V1	1532 24 Aug 2020	30	1623 MR 24 Aug 2020	1637 MR 24 Aug 2020	1638 24 Aug 2020 MR	MR 24 Aug 2020
11281177	V1	1559 24 Aug 2020	30	1632 24 Aug 2020	1645 24 Aug 2020	1650 24 Aug 2020	MR 24 Aug 2020
11281178	V1	1723 24 Aug 2020	30	1740 24 Aug 2020	1742 24 Aug 2020	1750 24 Aug 2020	MR 24 Aug 2020
11281179	V1	1745 24 Aug 2020	30	1820 24 Aug 2020	1830 24 Aug 2020	1834 24 Aug 2020	MR 24 Aug 2020
11281182	V1	1057 25 Aug 2020	30	1135 25 Aug 2020	1148 25 Aug 2020	1154 25 Aug 2020	MR 25 Aug 2020
11281181	V1	1053 25 Aug 2020	30	1135 25 Aug 2020	1148 25 Aug 2020	1154 25 Aug 2020	MR 25 Aug 2020
11281183	V1	1114 25 Aug 2020	30	1208 25 Aug 2020	1219 25 Aug 2020	1228 25 Aug 2020	MR 25 Aug 2020

JSN0494

LABORATORY SAMPLE PROCESSING LOG

Protocol: C4591001 | **PI: Mark Koch, MD** | **Site: 1128**

Laboratory: Covance | **Sampling Type: Blood**

Subject Number	Visit Date	Draw Date/Time Thoroughly mix the blood by inverting the tube five times	Total Clot Time in minutes	Time in Centrifuge (samples should be spun at 1500-2000 x g for at least 15 minutes	Aliquoting Date/Time	Date/Time in -20°C freezer for Plasma samples (Freeze immediately)	CRC Initials/Date
11281165	V1	24Aug2020 @0947	30	1040 24Aug2020	1044 24Aug2020	1045 24Aug2020	MQ 24Aug2020
11281166	V1	24Aug2020 @1114	30	1213 24Aug2020	24Aug2020	24Aug2020	MQ 24Aug2020
11281167	V1	24Aug2020 @1129	30	1213 24Aug2020	1235 24Aug2020	1257 24Aug2020	MQ Aug/24/2020
11281169	V1	1140 24Aug2020	30	1213 24Aug2020	1235 24Aug2020	1257 24Aug2020	MQ 24Aug2020
11281168	V1	1222 24Aug2020	30	1300 MQ 24Aug2020	~~[illegible]~~ MQ 1335 24Aug2020	1338 24Aug2020	MQ 24Aug2020
11281171	V1	1304 24Aug2020	30	1332 24Aug2020	1354 24Aug2020	1356 24Aug2020	MQ 24Aug2020
11281172	V1	1304 24Aug2020	30	1332 24Aug2020	1339 24Aug2020	1339 24Aug2020	MQ 24Aug2020
11281170	V1	1315 24Aug2020	30	1354 24Aug2020	1354 24Aug2020	1424 24Aug2020	MQ 24Aug2020
11281175	V1	1412 24Aug2020	30	1447 24Aug2020	1519 24Aug2020	1522 24Aug2020	MQ 24Aug2020

JSN0495

Ex. 26

Brook Jackson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, September 10, 2020 11:11 AM
To: Kandy Downs; Brook Jackson
Subject: **PLEASE READ** Source Completion & Clinical Conductor Visit Reconciliation Requirements

Importance: High

I wanted to send this as a reminder, Kandy, that we have to make sure our sites are completing all visits in Clinical Conductor (CC) BEFORE leaving for the day. Brook, I can show you how to check CC to ensure this is being done. I put an Outlook reminder on the calendar for my sites- not sure how you're doing it, Kandy, but this has helped some, but they do get behind still. We need to be adding this to our performance evaluations, please. Executive leadership will hold us all responsible if it's not getting done. Also Brook- please see the email below this that I sent out recently to everyone about these requirements.

Per a previous Daily Status Update by Mercedes:

Mercedes

- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance. See below. I only see two pending patients
    - Show the following still pending apts.
        - 8/1- all Burleson (see attachment)
        - 8/17- all Houston (see attachment)
        - If all of these aren't completed by EOB today (and pending apts from today moved over, there will be write-ups for the SOM and RD)
        - Please have your sites take care of them, and moving forward, you guys need to be checking the check-in/check-out for the current day and the day before when you send your daily update. If there are still pending apts at your sites when you send your 4:00 update, that is the perfect time to get on the phone to your site and get them to start moving apts over.

Thank you both,
Marnie

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Thursday, August 13, 2020 5:12 PM
To: Ventavia <ventavia@ventaviaresearch.com>
Subject: **PLEASE READ** Source Completion & CC Visit Reconciliation Requirements
Importance: High

Hello everyone,

Please make note of a few critical reminders and new instructions:

1. **ALL source documents MUST be completed in real-time with patients**, at the time of the visit- before leaving the patient's room. DO NOT delay completing source to the end of the day- we must be completing every blank, every footer, etc., at the time of the visit, with no exceptions. The patient chart should be completed so that by

JSN0496

the time one is done with the chart, it can easily be passed on to be QC'd, scanned into Complion, and then entered into eDC. And this applies to all studies, not just COVID. Please remember, this data has to be completed regardless- either on the frontend or the backend. The problem with choosing the backend, is now the time has passed so data or assessments have been forgotten, source may have already been scanned in, signatures were missed and now the investigator is not available to sign. This results in deviations, queries, and overall will jeopardize the integrity of the data and ultimately our reputation and future access to studies and thus revenue coming in.

2. Given the critical nature of this, patient charts will be spot-checked at all sites for "audit readiness" and if source is found to be incomplete, performance counseling will be issued.

***We MUST be audit-ready at ALL times**. The FDA can walk into a clinic tomorrow, completely unannounced, and review any chart they want to. Everyone should be leaving their clinic for the day knowing that patient charts can be reviewed at any time by anyone, and have no doubt that we would pass any surprise audit.

3. The same goes for **reconciling all visits in Clinical Conductor-** this must be done by the end of the day BEFORE leaving for the day. There should be no "pending" visits left on the calendar. This is crucial for many reasons but mostly to ensure adequate and timely study reimbursement, but also to ensure we all have real-time and accurate scheduling information.
4. Lastly, this is a new item that we are implementing immediately- we need to **capture race for all patients.** We already record this in our source documents, but we will be documenting this on the Patient Information Sheet that is completed on all patients so that we can upload this as well into Complion. I have revised the form to include this, below is the link to the new form in SharePoint:

https://netorg18834.sharepoint.com/:w:/g/EVJKnP9DI_xGoo7DXJrH7OsBGyPLSuKnARD3sOKedTrZuw?e=bvjYUw

Please let me know if you have any questions or concerns and please ACKNOWLEDGE that you have read this email.

Thanks all,

Marnie Fisher
Director of Operations, MBA, BSN, RN

Ventavia Research Group
1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817.269.3768
eFax Number: 817.394.1901
Email: mfisher@ventaviaresearch.com

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

Ex. 27

To: Marnie Fisher[mfisher@ventaviaresearch.com]; Brook Jackson[bjackson@ventaviaresearch.com]; William Jones[wjones@ventaviaresearch.com]
Cc: Mercedes Livingston[mercedeslivingston@ventaviaresearch.com]; Olivia Ray[oliviaray@ventaviaresearch.com]; Kristi Raney[kristiraney@ventaviaresearch.com]
From: Kandy Downs[kdowns@ventaviaresearch.com]
Sent: Thur 9/24/2020 8:52:58 PM (UTC)
Subject: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096_COVID-19 Symptom Surveillance Log
Pfizer_C4591001_COVID Surveillance Review Log_19AUG2020.docx

Here is the Weekly COVID log, dated 19Aug2020- but none of the sites have been using this.

This needs to be placed in the charts and goes with the NTF for being not used, but weekly trialmanager reviews, are, were being conducted.

Warmest Regards;

Lovica "Kandy" Downs
Regional Director
RMA, BBA, CCRC

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell Number: 817-269-5997
eFax Number: 817.394.1901

Email: kdowns@ventaviaresearch.com

VRG VENTAVIA RESEARCH GROUP PLATINUM RESEARCH NETWORK

https://www.ventaviaresearch.com/ *http://www.platinum-research.net/*

From: Kathryn Weems <kathrynweems@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 1:28 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Subject: Fw: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096_COVID-19 Symptom Surveillance Log

Resending! See email below as well.

Kathryn Weems
Regulatory Coordinator
Ventavia Research Group

1307 8th Avenue 6124 West Parker Rd 1919 N Loop W

Suite 202
Ft. Worth, TX 76104
817.348.0228 Office
817.394.1901 eFax

Suite 134
Plano, TX 75093
972-520-0003 Office
972-981-7749 Fax

Suite 250, 280
Houston, TX 77008
832.831.5349 Office
346.335.1186 Fax

300 N Rufe Snow Drive
Keller, TX 76248
682.774.8013 Office
817.337.3224 Fax

1733 Precinct Line Road
Hurst, TX 76054
682.774.8013 Office
817.337.3224 Fax

From: Kathryn Weems <kathrynweems@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 11:44 AM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>
Subject: Fw: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096_COVID-19 Symptom Surveillance Log

Hello,

It seems that I did initially create a COVID-19 Symptom Log, but it was buried during review. I sent it out to the lead CRCs (which, at the time, Becca was helping out with this study) and Dana, but never heard back and thus... it was left untouched.

Please review to see if this solves any issues with COVID-19 symptom surveillance.

Regards,

Kathryn Weems
Regulatory Coordinator
Ventavia Research Group

1307 8th Avenue
Suite 202
Ft. Worth, TX 76104
817.348.0228 Office
817.394.1901 eFax

6124 West Parker Rd
Suite 134
Plano, TX 75093
972-520-0003 Office
972-981-7749 Fax

1919 N Loop W
Suite 250, 280
Houston, TX 77008
832.831.5349 Office
346.335.1186 Fax

1733 Precinct Line Road

300 N Rufe Snow Drive
Keller, TX 76248
682.774.8013 Office
817.337.3224 Fax

Hurst, TX 76054
682.774.8013 Office
817.337.3224 Fax

From: Kathryn Weems
Sent: Wednesday, August 19, 2020 11:05 AM
To: Rebecca Iacullo <rebeccaiacullo@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>; Thea Sonnier <tsonnier@ventaviaresearch.com>
Cc: Dana Duvak <danaduvak@ventaviaresearch.com>
Subject: Pfizer C4591001_Koch|1128, Fuller|1085, Tran|1096

Hi ladies!

You requested for me to create a COVID symptom review log for eDiaries. On Becca's recommendation (thank you Becca!!), I based it on the RSV surveillance log from the maternal RSV study. I have created and attached the initial draft based on the protocol and the Trialmanager user guide. If you note anything that should be added or removed, please send back with the document and tracked changes on (or highlighted so I can see the change), and explanation on why on the email body! That way I can solve any issues quickly!

If you all are fine with the new source and its good to be used for this study, I will finalize this study source.

Regards,

Kathryn Weems
Regulatory Coordinator
Ventavia Research Group

1307 8th Avenue
Suite 202
Ft. Worth, TX 76104
817.348.0228 Office
817.394.1901 eFax

6124 West Parker Rd
Suite 134
Plano, TX 75093
972-520-0003 Office
972-981-7749 Fax

1919 N Loop W
Suite 250, 280
Houston, TX 77008
832.831.5349 Office
346.335.1186 Fax

300 N Rufe Snow Drive
Keller, TX 76248
682.774.8013 Office
817.337.3224 Fax

1733 Precinct Line Road
Hurst, TX 76054
682.774.8013 Office
817.337.3224 Fax

C5691001

Weekly Subject COVID Symptom Review Log

Date of Vaccination 1: _____________ **Date of Vaccination 2: _____________** ****TrialMax reports are to be printed once page is completed****

Study Week	Site Team Date of Review	Initials of Reviewer	Any COVID Symptoms or events entered in eDiary?		If no/incomplete data entered, subject was called, or if subject received any tests (NAAT, Rapid Antigen, molecular diagnostic), enter here.
			☐ None ☐ A diagnosis of COVID-19 ☐ Fever ☐ New or Increased Cough ☐ New or Increased shortness of breath ☐ Chills ☐ Any other respiratory symptom of concern	☐ New or increased muscle pain ☐ New loss of taste/smell ☐ Sore Throat ☐ Diarrhea ☐ Vomiting	
			☐ None ☐ A diagnosis of COVID-19 ☐ Fever ☐ New or Increased Cough ☐ New or Increased shortness of breath ☐ Chills ☐ Any other respiratory symptom of concern	☐ New or increased muscle pain ☐ New loss of taste/smell ☐ Sore Throat ☐ Diarrhea ☐ Vomiting	
			☐ None ☐ A diagnosis of COVID-19 ☐ Fever ☐ New or Increased Cough ☐ New or Increased shortness of breath ☐ Chills ☐ Any other respiratory symptom of concern	☐ New or increased muscle pain ☐ New loss of taste/smell ☐ Sore Throat ☐ Diarrhea ☐ Vomiting	
			☐ None ☐ A diagnosis of COVID-19 ☐ Fever ☐ New or Increased Cough ☐ New or Increased shortness of breath ☐ Chills ☐ Any other respiratory symptom of concern	☐ New or increased muscle pain ☐ New loss of taste/smell ☐ Sore Throat ☐ Diarrhea ☐ Vomiting	
			☐ None ☐ A diagnosis of COVID-19 ☐ Fever ☐ New or Increased Cough ☐ New or Increased shortness of breath ☐ Chills ☐ Any other respiratory symptom of concern	☐ New or increased muscle pain ☐ New loss of taste/smell ☐ Sore Throat ☐ Diarrhea ☐ Vomiting	

Date report was printed: __ __/__ __ __/__ __ __ __ COVID-19 Symptom/Event Review Report Printed by: ________

Subject Initials/Number: __ __ __ / ____________

Page __ of __

JSN0502
Version 1 19Aug2020

C4591001

Weekly Subject COVID Symptom Review Log

Ensure that the Schedule of Activities are reviewed for the subject if they are confirmed to have COVID symptoms or events. During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with solicited systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit unless, in the investigator's opinion, the clinical picture is more indicative of a possible COVID-19 illness than vaccine reactogenicity. Subjects will be prompted to report COVID-19 symptoms or events until Visit 6 is completed, in which the site will either collect the e-diary at this visit or assist the participant to delete the application. Use the comments below to address any other issues when filling out the COVID Symptom Review Log. This could include events such as:

- Subject is contacted by phone.
- Subject sent alert to site via e-mail.
- Potential COVID-19 Illness Visit is scheduled
- Potential COVID-19 Illness Visit is scheduled but not completed
- If any further information is collected from subject upon contact.
- Potential COVID-19 Illness Visit not scheduled; subject unable to complete visit (scheduling issue)
- Potential COVID-19 Illness Visit not scheduled – data entry error in eDiary (symptoms/event entered in error)
- PI determined that an assessment was not needed.

Additional notes (if applicable):

Subject Initials/Number: __ __ __ / ____________

Ex. 28

Daily Status Calls-Notes and Action Items

9/17/2020 Action Items

Kandy

- QC both unblinded logs at KEL and FW
- **Get ARL's screening visits canceled so Becca can immediately QC Keller**
- **Get Plano's visits handled by Precilia so Jill can immediately QC Keller**
- Check with William:
  - FDA training
  - Should HOU stop enrolling, ask William please
- Put a plan in place to schedule weekly touchpoints with your PI's
- Talk with JP
  - What did she mean that "Ventavia is going to get what's coming to them"?
    - Let he know how concerned Dr. B is about that
  - Go over Peppler's concerns-comments about being unhappy, unsupported, etc.
  - Go over professionalism, growth, examples that have been given
  - Have KB as a witness and make sure this convo is all documented and sent to us so we can make an informed decision (write up vs termination)

Marnie

- **Talk to Dr. Fuller about pausing enrollment**
- **Dana needs to help QC FW (we will push back novavax start a week or two, if needed, bc she will ask)**
- **JV needs to help QC FW**
- Get Mer out there when it's FDA ready
- Make sure both RD's set up a schedule to do weekly touchpoints with their PI's-oversee this

Brook

- Admin needs to be at desk at all times. Get coverage for restroom and lunch breaks. No folders of W9's there (explain to Becky), make sure nothing else is in sight.
  - Go through FDA training (auditor walks in, ask for identification, etc.)
- Talk to Jen about how we are putting subject's safety at risk and get specifics and report back to us asap
- Let Koch know that we are pausing enrollment
- Get Mer out there when it's FDA ready
- Put a plan in place to schedule weekly touchpoints with your PI's

Olivia

- Call Chrystal to stop scheduling
- Cancel visit 1's after 11am today and the rest of the week and next week (FW and KEL)
- Put patients on the schedule after 9/28

9/16/2020 Action Items

Mercedes

- Get references for Tiara
    - If good, then get a call with Medix

Brooke

- Make sure Keller and FW have the Firecrest amendment 6 training completed by this morning
- Speak to Jaz and have her go to Chrystal about communication with calling pts
- Speak to Jen Vasilio about overseeing Chrystal
- Continue to monitor recruitment efforts for FW and KEL-COVID

Marnie

- Call J.Valo and see what she wants, let her know when she has questions to come to Marnie first

Kandy

- Continue to monitor recruitment efforts for HOU-COVID

9/15/2020 Action Items

Kandy

- Focus on recruitment this week for HOU (Covid)
- Put the AZ issue in an email to all of us so we can come up with wording on how to respond to this
- Get hard confirmation from Univision about going live on Thursday
- Talk to Christine about sub-leasing contract
- Talk to Alma about going back to Burleson, work with Marnie/Brook about FW exit plan
- Talk to Jill about goal date of 9/21 for PM start, in the meantime, work with Dana on looking at checklists (tailoring it to fit mat rsv studies), PM job description, etc.
    - Get Precilia added to the other studies
- Talk to Cordy about Arlington (fast and furious, no mileage) vs Burleson (slower)
- Send Univision email statement to Katie Buchanan

Marnie/Brook

- Keep a close eye on Katie/Keller's enrollment numbers, she needs to continue to try and schedule the full 60 for the week. If she's having a challenge with less CRC's, she needs to loop us in before Chrystal decides to stop scheduling patients.
- Work with Chrystal this week to get numbers up, check on CC list for 16 and 17 yr olds (or waiting list?)
- Focus on the recruitment this week for FW and KEL (Covid)
- Help with Alma exit plan

Mercedes

- Check with Kate on Amend. 6 ICF
- Give directive to sites and recruiters if we can start enrolling 16 and 17 yr olds

  - ICF IRB approved and received by sites
  - Amend 6 firecrest training completed
- Follow up with reg person about hours and schedule

Olivia

- Find Medix contract
- Find HOU lease

9/14/2020 Action Items

Olivia

- Get with Katie about bamboo HR and salary info in the system
- Get with Katie about moving PI/Sub-I/Pre-screening physician onboarding to the RD's on the checklist (CV's, trainings, etc.)
- Run email by her

Kristi

- Call Pam about reaching out to the news stations in DFW
- Write up something generic for news stations

Kandy

- Let sites know to reach out to James/Burt when they need help filing so they can knock it out
- Identify a scanner
- Get Univision ad ran today
- Get in touch with Christine to see if Lizatte can call Syan Rhodes about a follow up story, and then all other HOU sites
- Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week**
- Talk to Christine about extending Tony's contract if he can
- Talk to Becca about staying in ARL for right now, and have her go to Dallas one day this week to QC

Marnie/Brook

- Can you have J. Valo work in GRA on Wednesday
- Get with Katie Buchanan to add J.Valo to timeco
- Jailyn-help email, make sure it was dealt with (with Jen Vasilo), please get Jailyn in a better place (documented games plan to get things distributed)
- Let sites know to reach out to James/Burt when they need help filing so they can knock it out
- Reach out to Jen Vasilo about Jerred's load and let him know about Katie Buchanan pulling him to work with her (newsletter, bamboo HR/timekeeping system, etc.)
- Identify a scanner
- Get with Angela about adding onboarding newhire for the next two weeks, OT approved if needed (submit to Marnie or Mer for approval??)
- Stay on your SOM's to get the missing certifications, PI/SubI stuff done **this week**

Mercedes

- 9/9-WEA, 9/12-DAL, 9/13-WEA, DAL, HOU-Pending Visits in CC
- Call Andrea back about raising the offer

9/11/2020 Action Items

Kandy

- Precillia review to Mer
- Tell Christine to make second interview rounds and narrow it down
- Talk to Mark about helping with reg

Marnie/Brook

- Get reviews to Mercedes (April, Kati D, Rebecca Mateos)
- Talk to Katie Benitez and Jen Vasilio about getting all EDC and internal queries done by EOB today or EOB tomorrow

Mercedes

- Work with Shannon to get freezer excursion reported to the sponsor
- Have Shannon talk to Dr. Pero about freezer being unplugged and moved, and the consequences it caused
- Have Shannon expense her hotel room
- Call DFW candidates
- Resend W9 email
- Send out email for mat rsv sites to send email when baby is born, RD, SOM's, etc.
- Send an offer to Kati D's referral and FW admin

9/10/2020 Action Items

Marnie/Brook

- Marnie to follow up with Kate Weems again, discuss her attitude and phone etiquette (conversation with Mercedes yesterday) find out what's going on with her- where's the "old happy Kate".
- Brook to reach out to Kate Weems to schedule one-on-one introduction and request Complion training- Brook will get a feel for what's going on with Kate as well.
- Stay on top of Chrystal today to ensure recruitment scheduling goals are being met, per Kristi's instruction and if not, what's her game plan:
  - This week- Houston 40, FW 60, Keller 60
  - Next week- Houston 100, FW 60, Keller 60
  - Following M-W- Houston 100, FW and Keller at least schedule 25 per day.
- Follow-up with Chrystal to see if they have reached out to other offices in the building to recruit.

Kandy

- QC MAT RSV charts in FW

- Continue reviewing resumes and will forward those recently reviewed to Kristi/Mercedes

Mercedes

- Follow-up with candidates (Lori/Kati D referral- will make offer)
- Shadow Angi and Alicia in Keller- review some of their charts

----

9/9/2020 Action Items

Mercedes

- Reach out to Katie Buchanan to get a job description to send to Anne as a Research Assistant
- Get with Angela to go through all maternal visits and see that they are being completed correctly
- Contact hospitals to see what we have to request to get the congenital heart screening document that has Pulse Ox on it
- Follow-up with maternal sites to get IMPALA updated

Marnie/Brooke

- Ensure the review that was completed with Anne yesterday was sent to Katie Buchanan for filing
- Speak with Anne about regulatory background
- Kandy review to Mercedes
- Reach out to Jen Vas to see if FW needs another mini fridge/-20 freezer for FW
- Talk to Jennifer Valo about maintenance Project Manager role- starting next week
  - Need to get with Dana on templates and checklists for the role
- Send email to project managers (Jennifer, Jill and Dana) reminding them to introduce themselves when reaching out for the first time, be kind
  - Role is to build a relationship between the sites
- Send out a company wide email regarding Project Managers
  - Dana over adult COVID
  - Jill over Maternal studies
  - Jennifer Valo over maintenance studies
- Send a shout out for Kati D enrolling 4 maternal patients yesterday

Kandy

- Create job description/step by step guide as to what makes a good Research Assistant
- Precillia review to Mercedes
- Jennifer Payne review to Mercedes
- Will look at resumes
- Get mini fridge and freezer from room 4 in FW to Arlington 2nd location
- Prioritize Becca on getting the job outlines for positions

- Reach out to Jill to see if she had
- Look for staff on Indeed, etc for the following openings
    - CRC for Plano, Arlington, RA (Arlington), Keller, FW
    - Recruiter for HOU
- Follow-up with FW to see if Thea hand cut was written up

9/8/2020 Action Items

Mercedes

- Send Dana the job description for the PM role for starting tomorrow, she needs to send a daily report everyday before she's done, create a checklist from the script, and SIV's should be first priority (by the 23rd or before), and if she can't get to the source she needs to wave the white flag so we can have Becca step in and do it. Have convo with her about working from home and kid's distractions.
- Ask Marnie if she sent the SIP email.

Kandy

- Work on Univision thing
- Get reviews to Mercedes

9/4/2020 Action Items

Kandy

- Radio script/TV ad, send to K/M/O

Olivia

- Send VRG logos to Kandy

9/3/2020 Action Items

Mercedes

- Get Angela ready to go remote next week
- Get resume from Kati Dykes to call and interview

Marnie

- Let Kate know that writing emails or slacks about x, y, z is a time-waster and she is spinning her wheels. She is not in a position to be giving her opinion of what we should be doing as a company (take the study, don't take the study, site too busy, questioning why the owners are asking her to do a reg packet as a priority when the reg letter said it could be done in 10 days, etc.). Writing these long emails is taking time away from all the other stuff she should be doing and is super stressed about. She is OOTO until Tuesday.
- Send an email company-wide looking for very strong CRC's and shout out to everyone about how we are building infrastructure, etc.

- Type up email regarding mileage
- Get with admins at each covid site about purchasing bins/baskets (make sure they look ok/nice) for bottled water and pre-packaged snacks to have available for patients during high enrolling study days (order everything online to always have available and in sight for patients)

Kandy

- Get with Christine to talk to Tran about the space (hire more staff, control employees better, not having to go up and down stairs to see patients,
- Send Telemundo pricing to us
- Get HOU ad to us today
- Talk to Christine about getting their OT under control once enrollment stops
- Have Jerred create a cheat sheet for all sites regarding saving an email in a pdf
- Tell Becca to keep her emotional feelings out of emails, try to stick to the facts
- Christina-review, need to get it ready, address the toll issue
- Talk to Jill about PM role and getting her moved over, also about making sure christina is being trained and shadowed

9/2/2020 Action Items

Mercedes

- Talk with William about his recommendations for QC employees
- Log into Firecrest to see if we have a radio ad already approved by Pfizer
- Talk to Haily, Elyza, and Jessica today so we can make a decision on Erin
- Oversee the Inv onboarding email
- Pending visits in CC in ARL the last couple of days
- Send an email chain to get status update at end of each day, how many they got to, etc. Any glaring findings? Set an alarm.

Marnie

- Talk to JV to try and consolidate all her doc appts into one day, make sure she's clocking out for these appts-if it continues, let's loop Marisa and Mercedes in. Document and give to KB for filing.
- Look at reviews and get a game plan
- Keep an eye on Anne's QC'ing, look at her chart that she has QC'd to check her work
- Review Kandy's SO verbal warning doc before submitting to K.Buch
- Look for KB's email and about certifications and Kate Weems email re: Inv onboarding

Kandy

- NTF for Keller temp log excursion
- Look at reviews and get a game plan
- Complete a SO verbal warning document re: Anne and have it reviewed by Marnie quickly
- Call HOU to see what is going on with the news spot
- Look for KB's email and about certifications Kate Weems email re: Inv onboarding

9/1/2020 Action Items

Kandy

- Look at resumes for CRC's for almost all sites

Kristi

- Email KB about setting up mediation session

Mercedes

- Tell Jen Vas to turn in verbal to KB, not have Niki sign

8/31/2020 Action Items

Olivia

- Reactivate HOU ad?

Mercedes

- Tell Erin we are still interviewing
- Pending visits in CC

Kandy

- Have Cordy do the first vaccine on the phone with her
- Dallas-IRB documentation emails
- Keller phlebotomist email-follow up with Katie (Cara Lopez-rate)
- Let Olivia know if we need to activate HOU ad tonight
- Help with Katie B email re: investigators

8/27/2020 Action Items

Mercedes

- Reach out to Erin re: medical records
- Go through Kate's email and reach out to Becca about source (Pfizer Mat RSV and COVID)
- Kate-OT approved, talk to her about training William
- Final interview/vet Erin McLeod, approval to hire for FW, 57k

Olivia

- Reach out to JV, DD re: new roles
- Send role email to Kandy to the chain
- Oversee covid-19 recruitment numbers while Kristi is out

Kandy

- Reach out to Christine, Lizatte, Jill re: new roles
- Go to sub-I mess of an email and handle Marnie's sites also
- Angi training for Pfizer mat rsv over the weekend

- Reach out to KB in KEL about EDC entry

8/26/2020 Action Items

Mercedes

- Reply to email KEL about month to month lease
- Change in OM to always schedule PSSV's as early in the window as possible

Marnie

- Pending visits in CC-see Mer's email (DAL, ARL, HOU)
- Check on unblinded situation for KEL
- Work with Jen Vasilio about Saturday clinic for covid-19
- Need to make KEL and FW understand that in order to get the $500 stipend, they need to work whatever it takes (late nights and Sat clinics) to get close to their enrollment goal each week

Kandy

- Pending visits in CC-see Mer's email (DAL, ARL, HOU)
- Call Kate and ask her to resubmit PSF for COVID-19 (from CC) ASAP
    - IRB approved autoimmune diseases, incl T1 diabetes (but this is incorrect and needs to be removed)
- Work with Chrystal to figure out how to identify and contact any subjects we inadvertently PS failed bc of T1 diabetes and re-PS for scheduling

8/25/2020 Action Items

Mercedes

- Call Deedra and offer ARL
- Get with Marnie and decide who needs to get added to Keller PSSV

Marnie

- JV-speak about racial comment, have a verbal coaching/mentoring moment (racial tendency and negative attitude towards leadership) (ex. Slave driver and "being illegal" vs undocumented)
- Get with Mer and decide who needs to get added to Keller PSSV
- Let Alma know that Mer will handle BUR tomorrow
- Get with your COVID sites and have them call and move up anyone who is scheduled past two weeks out, bc study might close
- Work with FW on getting more scheduled to get 60 this week, have Chrystal email Meagan and ask her to check the info@ven email every 24 hours and forward all participant emails each day (whenever Meagan plans to work (at night, mid-day, whatever). If Chrystal or other recruiters need to login to get emails sooner, the password is Research1!
- **Be the VRG employee whisperer!!! haha**

Kandy

- Get with your COVID sites and have them call and move up anyone who is scheduled past two weeks out, bc study might close
- Work with JP on SAE narrative

8/24/2020 Action Items

Kristi

- Task Becca with calling healthcare facilities surrounding KEL, FW, HOU for reaching out to their employees about the study, all school districts (for their employees), churches, daycare employees

Mercedes

- Make sure KEL schedules PSSV this morning (make sure to tell them to mention access to minorities and healthcare workers)
- Call Arturo to speak on behalf of FW and KEL and minorities
- Pending visits in CC Aug 20th

Olivia

- Boost old HOU ad on FB
- Do HOU ad again for CRC

Marnie

- Check on PSSV time today for Novavax (make sure to mention access to minorities and healthcare workers), grab JV or Angela for any VRG specific questions
- Offer the $500 weekly stipend to all FW clinic employees willing to work OT/Sat clinics to get these 60 in, manager needs to collect the employees' names and submit these stipends to payroll at each run, cc Kristi, Olivia, Mercedes, so payroll knows its legit
- Thea-speak to her about urgent matters, she should have told us RIGHT way, we could have had all weekend to schedule and plan for this week. This is a HUGE deal. Verbal warning. Now we might have lost 20 pts for this week. This was hundreds of thousands of dollars on the line. If she emailed it on Friday, the email needs to be forwarded to us.
- Get Janssen game plan going for season 2 participants (49 pts, 3 hours visits, starting Sep 7th?)
- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion
- Pending visits in CC Aug 20th

Kandy

- Find another HOU CRC
- Send over recent onboard lists
- Speak with Alma about helping in FW until we have someone else hired
- Get on Dallas/Arlington email to figure out sub-I signatures
- Let your sites know, anything that would be printed and put in hard reg binder, needs to be uploaded to Complion

- COVID 1001 DOA log updates-HOU
- Pending visits in CC Aug 20th

8/21/2020 Action Items

Kristi

- Send email out to all remotes to see if they need a new scanner

Olivia

- Amend Indeed ad to include ARL
- Send email to JV with updates

Marnie

- Go read Olivia's Becca email carefully

Kandy

- Order the drop-down desks
- Get with all sites about ordering scanners
- Work with Shannon on sending PD's to the IRB, and creating a dummy chart
- Talk to Christine
    - Turn in the $1000 bonuses to payroll each payroll week and she can cc Kristi/Olivia/Mercedes so payroll knows it's legit
    - See about putting someone in Tran's office to get more covid pts scheduled
    - Work on messaging and over scheduling to compensate for huge no shows
    - Call Garza's pts who have appts to see if they want to come to VRG after for an appt
    - Lottery thing
    - Offer pizza
    - Order the fridge

8/20/2020 Action Items

Kandy

- Call HOU RD to see if interested in contract QC position, get rate, ask about travel to DFW if she were to get the RD position
- Get HOU to create a schedule for COVID enrollment
- Create a site plan to recognize holes

Marnie

- Get office organized, get desk setup-bring in Angela's son to help with all of this
- Create a site plan to recognize holes
- Speak to Katie about overseeing both sites for a few weeks

Mercedes

- Get Brook's offer out

8/19/2020 Action Items

Kristi & Olivia

- Speak with Becca about new role

Kandy

- Find an employee to hire to upload Complion for COVID-19
- Find or delegate someone to find a high-speed/high volume scanner to purchase for sites that need it
- Finish write up and send to everyone for review
- Get with HOU regarding 5 pending visits in CC from 8/17

8/18/2020 Action Items

Mercedes

- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance.
- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit

Marnie

- Talk to your COVID sites
  - As soon as they have a no show, call the recruiter and tell them to fill the spot
  - Schedule 20 Mon and 20 Tues, and 8 pts for Wed (in case recruitment cannot replace N/S's on Mon/Tues) If we hit our 40 by Tues, then move Wed's 8 pts to the following week.
  - Pull up CC and account how many are short
- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance.
- Talk to Jennifer Vasscilio about possibly going to HOU
- Talk to maternal calls, on call phones need to be with them at all times. Mom's are starting to deliver. Patients, staff, doctors are to ONLY call on call phone. Not personal phones!
- Follow up with newhire (Angi's friend—can't remember her name)
- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit

Kandy

- Talk to your COVID sites
  - As soon as they have a no show, call the recruiter and tell them to fill the spot
  - Schedule 20 Mon and 20 Tues, and 8 pts for Wed (in case recruitment cannot replace N/S's on Mon/Tues) If we hit our 40 by Tues, then move Wed's 8 pts to the following week.
  - Pull up CC and account how many are short
- Pending visits in CC since 8/12. Yesterday, there are still 25 pending visits. If sites do not know how to complete these, reach out to Angela for guidance.

- Talk to maternal calls, on call phones need to be with them at all times. Mom's are starting to deliver. Patients, staff, doctors are to ONLY call on call phone. Not personal phones!
- Think about Regional Director vs Support Specialist title, and who, internally, would be a good fit

8/17/2020 Action Items

Mercedes

- Confirm with Pfizer about what constitutes a week, can we get a head start on a Friday (as long as we don't go over 40 the following week), what is the window of IP
- Confirm with Pfizer that time IP needs to stay out and give proper directive to Marnie and Kandy, so they can let their unblinded staff know
- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.
- Get Burt's help to get the laptops set up in FW

Marnie

- Go over reconsent ICF process at all sites, not the admin's responsibility. The lead needs to manage this. She can assign the admin to put the ICF in the chart, but the admin realistically has no idea if a new consent has arrived.
- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.
- Let your SOM's know that sometimes we need to use kindness to deal with difficult patients (purchase lunch, a coffee, small gift card, apologize, etc.) Make it right when they are in the office, don't wait until they leave upset and go write reviews or report us to the IRB, FDA. Customer service is everything.

Kandy

- Find Olivia's email and get a plan for VRG, send to Kristi/Olivia
- Find Olivia's email and get a response back to Pfizer, cc Kristi/Olivia
- CC-visits still pending from the 7th, and maybe earlier. That's just the last day I finally stopped checking.
- Let your SOM's know that sometimes we need to use kindness to deal with difficult patients (purchase lunch, a coffee, small gift card, apologize, etc.) Make it right when they are in the office, don't wait until they leave upset and go write reviews or report us to the IRB, FDA. Customer service is everything.
- Get Dallas set up so Christina can go over and help ARL a couple of days a week

8/14/2020 Action Items

Olivia

- Check on FB commenting
- Clinical Conductor
    - Send instructions on how to pull visit statuses in CC

Mercedes

- Go over ediary issue with Kandy onsite in FW
- Offer OT to anyone who can come in and get things caught up on Sat

Marnie

- ~~Cordy send all logs to KD to verify it's correct~~
- Katie
    - Make sure they know to get their 64 in next week since they have no usable drug right now (24 leftover from this week and then the new 40 next week)
- Dana
    - Discuss scheduling friends or couples together, then take away the other spot. For example: 9 and 10 appt can turn into 2 at 9am and 0 at 10am
- Becca-stern talking to about the behavior, she needs to be acting as a mentor at any site, never singling or excluding people, remaining in KEL for COVID pts
- Nika
    - Move her to GV as soon as the new lady is ready to go on her own
- Make sure all sites have same complion plan in place for KEL, HOU, and FW
    - Initial and dating any blanks as everything might have already been uploaded
    - Have all sites give an update by EOB
    - Tomorrow needs to be worked to get everything caught up
- Offer OT to anyone who can come in and get things caught up on Sat

Kandy

- ~~Look over KEL's logs to ensure it's correct~~
- Make sure HOU has same complion plan in place as KEL and FW
    - Initial and dating any blanks as everything might have already been uploaded
    - Have all sites give an update by EOB
    - Tomorrow needs to be worked to get everything caught up
- Offer OT to anyone who can come in and get things caught up on Sat

8/13/2020 Action Items

Kristi

- Reach out to Kandy if you haven't received the GSK Mat recruitment email by EOB
- Dig around CC to track recruiters' record
    - Recruiters calling out vs taking incoming calls

Olivia

- FW recruiters
    - Take ad down

- HOU Staffing
  - Take the ad down for CRC
  - Keep ad for recruiter

Mercedes

- Get in touch with Arturo to check on Keller's IP
- Talk to JV
  - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed
  - Respect she needs to work remote
  - Help with WEA or maternal trainings as needed
  - Get Nikki trained on medical records ASAP, so she can start taking over next week
  - Still remain MR backup
  - Start assisting with source creation and PSF review/approval
  - Mercedes will also see what things you can assist her with
  - I really think there was more—but you will need to ask Mercedes to see what we are missing

Marnie

- Email ALL SITES for ALL VISITS: DO NOT LEAVE THE ROOM UNTIL SOURCE IS COMPLETE-Send email, write up if caught, FDA auditor will walk through the door at any second, high profile study, but this needs to be the standard for ALL STUDIES/ALL VISITS, no exceptions
- Check Clinical Conductor still pending visits for all sites
- Remind sites about drug waste
- Reminder (if needed), they have spent the last 6 months with coordinators MAYBE seeing one or two patients a week, yes it's busy, but come on now
- Talk to your sites about capturing race in CC when a patient comes in-mass email is fine
- Talk to Dr. Robbins about above issue, per Mer's email
- Talk to Angi, Becca, Nika, Cordy, etc, regarding gossip issue-replay she has been hired as an SOM for Dallas, she is training in KEL, they need to take her under her wing and mentor her
- Talk to Nika/Cordy about 3 pts she turned down, remind Cordy she can't make decisions without running them through Katie
- Get Katie back in Keller to manage COVID trial, find coverage for Grapevine
- Dana
  - Remind her about Nikki and the medical records
  - Pull Linda from lab and assign someone else
  - GSK MAT ICF issue email, possible trust issues with Linda and Jailyn
- Run complion upload by Kate and Mercedes, then give directive to site
- Chrystal-make sure FW gets the rest of their covid pts scheduled for the week

Kandy

- Talk to Christine
  - Create a same day list of patients to be "on call" for covid visits

- GSK Recruitment Plans-questions-send to Kristi
- Send email that Spanish translator doesn't have to be on the DOA Log so sites are aware
- Check Clinical Conductor still pending visits for all sites
- Remind sites about drug waste
- Reminder (if needed), they have spent the last 6 months with coordinators MAYBE seeing one or two patients a week, yes it's busy, but come on now
- F/U with HOU regarding COI for Tran

8/12/2020 Action Items

Kristi

- Send Jasmine resume to Katie Buchanan

Marnie

- Talk to JV
    - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed
    - Respect she needs to work remote
    - Help with WEA or maternal trainings as needed
    - Get Nikki trained on medical records ASAP, so she can start taking over next week
    - Still remain MR backup
    - Start assisting with source creation and PSF review/approval
    - Mercedes will also see what things you can assist her with
    - I really think there was more—but you will need to ask Mercedes to see what we are missing
- Talk to your sites about capturing race in CC when a patient comes in
- Dana
    - Remind her about Nikki and the medical records
    - Make sure Nadia is being utilized to full potential
    - **All COVID sites need to have a QC station prior to uploading into Complion (Alma)**
- Direct sites to do easier process for complion upload
- Watch Thea like a hawk

Kandy

- Talk to KEL and HOU about ediary issue
- **NIKA/ANNE: All COVID sites need to have a QC station prior to uploading into Complion**
- Direct sites to do easier process for complion upload
- Watch Thea like a hawk
- Call James if you have not talked to him already about EDC (214 208 0320)
- Complete CAPA for FW

8/11/2020 Action Items

Mercedes

- Call Arturo to confirm that drug received for KEL this week, can be utilized this week
- Make sure Angie sends resumes over

Marnie

- Cordy
  - Check in on her, see if there is another unblinded that can replace her so she can get back to recruiting
- Talk to Nika
  - Get Anne on the phones today, along with Alaina (do not pull them off the phones)
  - Check on drug
  - Make sure they are knocking out new drug in 2.5 days (16/16/8)
  - Make sure Katie is in Grapevine on Fri afternoon, so get help from someone else if needed
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them (Alma, Becca, Kati D, etc.)
  - Go over ediary issue/falsifying data, etc.
- Talk to Becca
  - Help create the schedule for KEL COVID
- Talk to Dana
  - Go over Mer's email re: COVID scheduling
  - Look at schedule ad drug, day by day and confirm if you need the additional help. If not, then please don't pull them
  - Go over ediary issue/falsifying data, etc.
- Chrystal
  - Tell her to change the visit time to 2 to 2.5 hours
  - She needs to train recruiters to start capturing race in CC
- Talk to JV
  - First round of interviews, give her specific questions to weed out, forward her any contenders from Indeed
- Talk to your sites about capturing race in CC when a patient comes in

Kandy

- Nikki-make sure unblinded for COVID (to free up Jailyn to see maternal pts), blinded for all maternal/pedi, eventual training on Medical Records
- Talk to Nadia (with Marnie)-can we get Nadia switched to onboarding/admin duties/take tasks over from Katie Buchanan for the next couple of months until Dana can take it back over. If she is, then please facilitate the process between KB and NM and the FW site to get this started.
- Talk to Christine
  - About the Complion upload station
  - Go over ediary issue/falsifying data, etc.
- Talk to your sites about capturing race in CC when a patient comes in

8/10/2020 Action Items

Olivia

- Hiring-Indeed Ads-Tweak to add the following
  - HOU-CRC, FW-CRC, KEL-2 CRC, 3-5 years' experience

Mercedes

- Get resume for Decatur for possible cord blood pickup and maybe CRC assisting if KD friend does not work out
- Interview Eddie
- Get Lorena onboarded for PRN calling/scheduling and cord blood pickup
- Draft up mat rsv deviation response

Marnie

- Get resume over from Kati Dykes-possible CRC asst
- Call Nika/Katie:
  - Anne needs to focus on scanning into Complion as much as possible this morning
  - Need to start scheduling starting Tues afternoon for new covid pts
- Call FW:
  - Get a game plan in place to get Complion caught up in EOB today
  - Move patients within their window to fit more COVID pts
  - Let Dana know Mer needs to know when they have a pedi blood draw due to so many deviations, so she can go up and draw
- Call Jennifer Valo that she needs to be in FW the rest of the week
- Call Chrystal and:
  - Direct John to call for KEL
  - Cordy cannot be responsible for KEL recruitment right now
  - Tell her OT is approved for nights and weekends so we can get spots filled
  - Let her know Shannon (anyone else), must call AND schedule
  - If newbies have questions, put them on hold and ask a seasoned employee, bc everyone needs to be trained and, on the phones, as soon as they can

Kandy

- Call Shannon and have her help call for COVID sites
- Follow up with Ashley-would she be a better fit in FW long term?
- Jasmine follow up
- Make sure Niki is trained on unblinded for COVID (to free up Jailyn), medical records and blood draws for maternal studies, train others on blood draws on pedis

Ex. 29

12:39

MF

Marnie >

Shoot, I don't have that invite. 7:59 AM

I'll fwd it, and see about a other laptop for you 8:00 AM

Tue, Sep 15, 7:32 AM

Good morning, did Keller still need help with scanning again today? Were u able to get through much? 7:32 AM

I didn't get one thing scanned. Katie handed me 5 charts that were "urgently" needed by Sponsor and not one had been QC'd. 7:52 AM

Oh! Okay. FW is behind in QC now. Do u want to go back to Keller to help scan and I can QC in FW? Or which would you prefer? 7:54 AM

I feel like either one is a trap😂 7:55 AM

I will go to either. 7:56 AM

Lol right. I will go to FW since I need to take the binders I picked up from Weatherford and then we can do our regulatory call at 1230 by zoom 7:59 AM

Should we review reg processes before hiring? 8:35 AM

Text Message